"Effect of structured exercise program on quality of life among menopausal women in selected areas of Bhopal: A randomised controlled trial."

Dissertation

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In partial fulfilment of the requirement for the degree of M.Sc. in Obstetrics and Gynecological Nursing

By

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I hereby declare that the dissertation entitled, **"Effect of structured exercise program on quality of life among menopausal women in selected areas of Bhopal: A randomised controlled trial."** is a bonafide and original work carried out by me under the supervision and guidance of **Dr. Naseema Shafqat (Guide)**, Assistant professor, Nursing College, AIIMS, Bhopal; **Mrs. Geeta Bhardwaj (Co-guide)**, Assistant Professor, Nursing College, AIIMS, Bhopal; and **Dr. Bharti Singh (Co-guide)**, Additional Professor, Department of Obstetrics and Gynecology, AIIMS, Bhopal. To the best of my knowledge, this dissertation or any part thereof has not formed the basis for the award of any degree, fellowship, or similar title to any candidate of any university.

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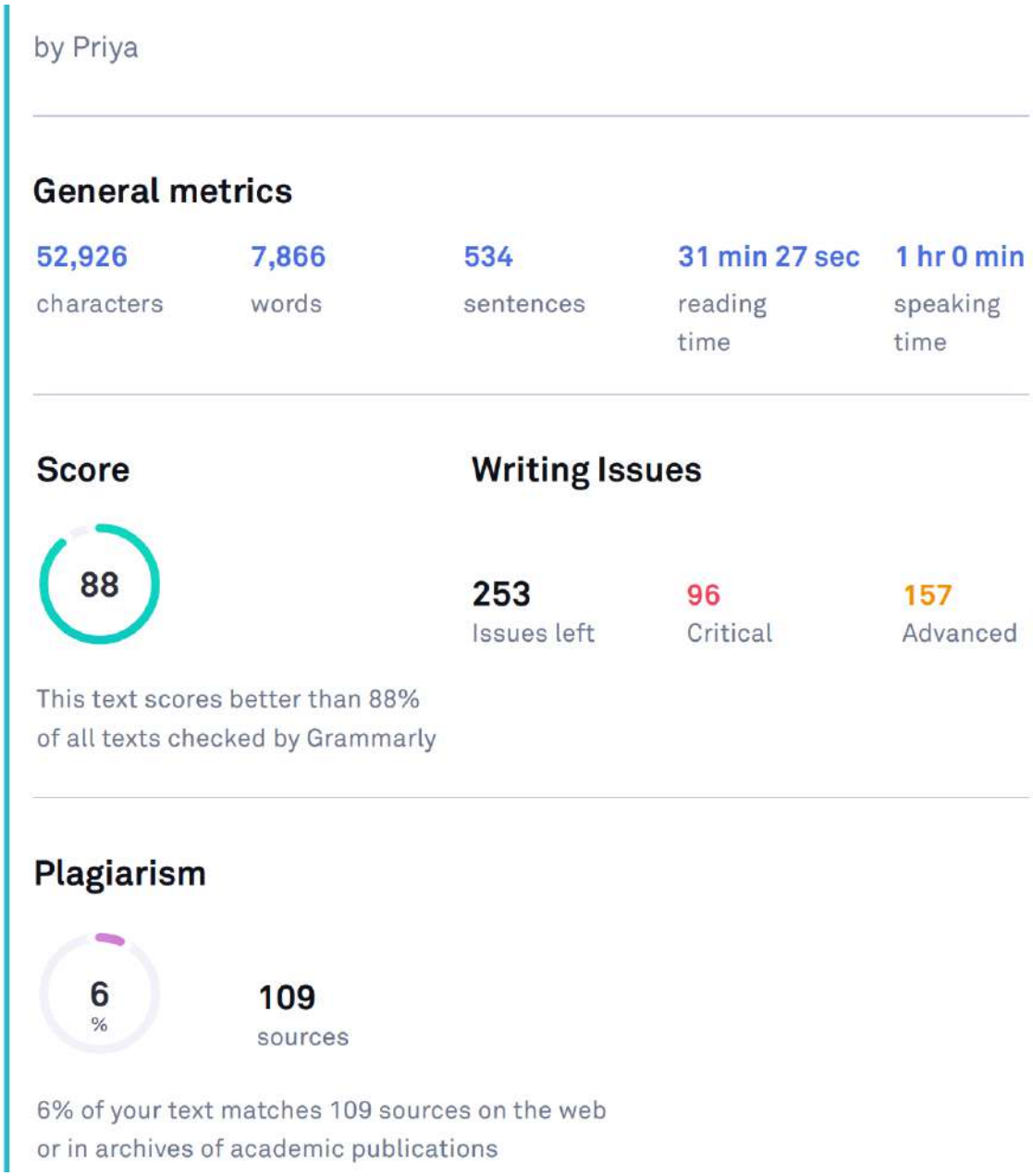

IHEC- SR LETTER OF PERMISSION

ALL INDIA INSTITUTE OF MEDICAL SCIENCES, BHOPAL
Saket Nagar, Bhopal – 462020 (M.P)
Institutional Human Ethics Committee- Student Research (IHEC-SR)
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Ref Number: IHEC/SR/2024/109 **Date: 1 Feb 2024**

Letter of Permission

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AIIMS, Bhopal Institutional Human Ethics Committee- Student Research (IHEC-SR) in its 9th meeting held on 1 Feb 2024 discussed your proposal titled **Effect of structured exercise program on quality of life among menopausal women in selected areas of Bhopal: A Randomised Controlled Trial** .

Following members attended the meeting:

Sr No.	Name/Post	Role
1	Prof. Manisha Shrivastava, Prof. & Head, Dept. of Transfusion Medicine, BMHRC, Bhopal	Chairperson
2.	Prof. Rajnish Joshi, Prof. & Head, Dept. of General Medicine, AIIMS Bhopal	Clinician Member
3.	Prof. Amit Agrawal, Prof. & Head, Dept. of Neurosurgery, AIIMS Bhopal	Clinician Member
4.	Prof Sunita Athavale, Prof. & Head, Dept. of Anatomy, AIIMS Bhopal	Pre-Clinical Member
5.	Prof Girish C Bhatt, Professor, Pediatries , AIIMS Bhopal	Clinical Member
6.	Dr. Sunaina Tejpal Kama, Additional Professor, Dept. of Anesthesiology, AIIMS Bhopal	Clinician Member
7.	Dr. Ujjawal Khurana, Associate Professor, Dept. of Pathology, AIIMS Bhopal	Para -Clinical Member
8.	Mr. Trivesh Goswami, Law Officer, AIIMS Bhopal	Legal Person
9.	Ms. Anjali Singh	Lay Person
10.	Prof. Neelkamal Kapoor, Former Prof & Head, Dept of Pathology, AIIMS Bhopal	Social Scientist
11.	Dr. Ankur Joshi, Additional Professor, Dept. of CFM, AIIMS Bhopal	Member Secretary

The decision of the committee is as follows:

The AIIMS, Bhopal IHEC-SR approves your research protocol. All research related activities must begin only after the date of this approval. The validity of this approval is till two years from the date of issuance. Please submit a closure report / renewal request before expiration of the validity for this approval.

Dr. Ankur Joshi
Member Secretary, AIIMS Bhopal IHEC-SR
Additional Professor, Community and Family Medicine, AIIMS, Bhopal

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"Gratitude makes sense of our past, brings peace for today, and creates a vision for tomorrow."

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Place: Bhopal Priya

Date: 28/02/25

ABSTRACT

Introduction

Menopause marks a critical phase in a woman's life, characterized by the cessation of menstruation and a range of physiological, psychological, and social challenges. Symptoms such as hot flashes, mood swings, sleep disturbances, joint pain, and decreased bone density can significantly impact the quality of life (QOL). In India, cultural perceptions, lack of awareness, and limited access to healthcare further exacerbate these challenges. While pharmacological interventions like hormone replacement therapy exist, structured exercise programs have emerged as an effective, non-invasive approach to managing menopausal symptoms. This study evaluates the effect of a structured exercise program on the QOL of menopausal women in selected areas of Bhopal.

Methods

A randomized controlled trial (RCT) with a pre-test and post-test design was conducted among menopausal women aged 45–60 years. Participants (n=102) were randomly assigned to an experimental group (structured exercise program) or a control group (routine activities). The intervention group participated in a six-week structured exercise program consisting of aerobic exercises, strength training, flexibility, and balance exercises. QOL was assessed using the Menopause-Specific Quality of Life (MENQOL) questionnaire at baseline and post-intervention. Data analysis was conducted using SPSS, employing descriptive statistics and inferential tests such as the Wilcoxon Signed Rank Test and Mann-Whitney U Test.

Results

The experimental group showed a significant improvement in MENQOL scores post-intervention compared to baseline ($p<0.05$), while the control group exhibited minimal changes. The structured exercise program led to reductions in vasomotor, psychosocial, physical, and sexual symptoms, enhancing overall well-being. A significant difference was observed between the experimental and control groups post-intervention, confirming the effectiveness of the exercise program.

Discussion and Conclusion

The findings suggest that a structured exercise program is an effective, non-invasive intervention for improving the QOL of menopausal women. Given the cultural and socioeconomic barriers to exercise participation in India, integrating structured exercise programs into community health initiatives could enhance menopausal health outcomes. Future research should explore long-term adherence and the impact of personalized exercise interventions.

Keywords: Menopause, Quality of Life, Structured Exercise Program, Randomized Controlled Trial, MENQOL

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LIST OF ABBREVIATIONS

S. NO.	ABBREVIATIONS	EXPANSION
1.	AIIMS	All India Institute of Medical Sciences
2.	M.Sc.	Master of Science
3.	QOL	Quality of Life
4.	MENQOL	Menopause-Specific Quality of Life
5.	HRQOL	Health-Related Quality of Life
6.	WHOQOL	World Health Organization Quality of Life
7.	MRS	Menopause Rating Scale
8.	SFQ	Sexual Function Questionnaire
9.	RCT	Randomised Controlled Trial
10.	IHEC-SR	Institutional Human Ethics Committee-Student Research
11.	PHC	Primary Health Centre
12.	I-CVI	Item Content Validity Index
13.	MeSH	Medical Subject Headings
14.	PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
15.	I-CVI	Item Content Validity Index
16.	SCVI	Scale Content Validity Index
17.	SPSS	Statistical Package for the Social Sciences

LIST OF SYMBOLS

S.NO	SYMBOLS	EXPANSION
1.	%	Percent/Percentage
2.	>	More than
3.	<	Less than
4.	≤	Less or equal to
5.	H_0	Null Hypotheses
6.	N	Sample size
7.	=	Equal to
8.	p	Level of significance
9.	f	Frequency

CHAPTER – I

INTRODUCTION

"Menopause is a natural part of life, and it's the end of one chapter, not the end of the book Quality of life is more than just living a long life. It's about embracing every stage of life with the courage to be your best self at every age."

1.1 Background of the study

Menopause is a significant phase in a woman's life that marks the end of her reproductive years. It typically occurs between the ages of 45 and 55, but it can happen earlier or later depending on individual factors[1]. Medically defined by the cessation of menstruation for twelve consecutive months, menopause is accompanied by a variety of physical, psychological, and social changes that can affect a woman's health and overall well-being. While menopause is a natural process, the symptoms that accompany it, such as hot flashes, night sweats, mood swings, irritability, anxiety, depression, and sleep disturbances, can have a profound effect on a woman's quality of life (QOL)[2]. The physical symptoms, including changes in metabolism and weight gain, muscle and joint pain, and an increased risk of chronic diseases like cardiovascular disease and osteoporosis, further contribute to the challenges faced by women during this phase[3].

In terms of psychological well-being, menopause often represents a time of personal and emotional turmoil. Many women experience feelings of loss, frustration, or even depression as they transition into this new stage of life[4]. The hormonal fluctuations that accompany menopause can exacerbate mood swings, leading to emotional instability. For some women, menopause can feel like the end of their youth or fertility, which can have a negative impact on their self-esteem and body image. Moreover, menopause is often an isolating experience, as

it is not always openly discussed in many cultures, and women may lack adequate support systems or information to manage their symptoms effectively.

The impact of menopause on quality of life is not limited to the physical and emotional aspects; it also extends to social functioning. Women may experience a decline in their social relationships and overall participation in social activities due to the physical and psychological symptoms they experience[5]. This reduced engagement in daily activities can also affect their professional and personal lives. When symptoms are not managed effectively, it can lead to a diminished sense of self-worth and a reduced quality of life. Consequently, menopause is now recognized as an important health issue that requires attention and appropriate interventions to improve the well-being of women going through this phase of life.

Quality of life (QOL) is a broad concept that encompasses an individual's perception of their overall well-being, considering aspects like physical health, psychological state, independence, social relationships, and environmental factors[6]. For menopausal women, QOL is often negatively impacted by the aforementioned symptoms. As a result, finding effective strategies to mitigate these symptoms and improve QOL during this phase is a key goal for health professionals. Interventions that address both the physical and psychological aspects of menopause are essential to enhancing the lives of women who are experiencing this transition.

One of the most widely recognized and recommended interventions for improving menopausal symptoms and overall well-being is physical exercise. Regular physical activity is known to have numerous benefits for both physical and mental health. Exercise can improve cardiovascular fitness, strengthen bones and muscles, and help maintain a healthy weight, all of which are particularly important for postmenopausal women[7]. Additionally, exercise has been shown to improve mood, reduce anxiety and depression, and enhance sleep quality. These benefits are particularly relevant for menopausal women, who are at increased risk for these issues due to hormonal changes and the physical and psychological demands of this life stage.

Structured exercise programs, which consist of planned and systematic physical activity, offer a more effective means of promoting regular exercise compared to informal or unstructured physical activity. Structured programs often include a variety of activities, such as aerobic exercises, strength training, flexibility exercises, and balance training, all of which have specific benefits for menopausal women. For instance, aerobic exercises like walking, swimming, or cycling can improve cardiovascular health, while strength training can help maintain bone density and prevent osteoporosis, a common concern for postmenopausal women[8]. Flexibility exercises, such as yoga or stretching, can help alleviate joint pain and improve mobility, while balance exercises can reduce the risk of falls, which become more common as women age.

Despite the growing evidence supporting the benefits of exercise for menopausal women, many women still fail to engage in regular physical activity, often due to a lack of knowledge, motivation, or access to appropriate programs. In India, this issue is further compounded by cultural attitudes towards physical activity and gender norms, which may limit women's participation in exercise, especially in more traditional or rural areas. Additionally, menopausal women in India may face barriers such as inadequate healthcare facilities, economic constraints, and a lack of awareness about the importance of physical exercise for health during menopause. Therefore, it is crucial to design and implement structured exercise programs that are culturally appropriate, accessible, and affordable for menopausal women, particularly in semi-urban and rural areas where resources may be limited.

This research seeks to address these gaps in knowledge and practice by investigating the effect of a structured exercise program on the quality of life of menopausal women in selected areas of Bhopal. By conducting a randomised controlled trial (RCT), the study aims to provide evidence on the effectiveness of a structured exercise program in improving both the physical and psychological well-being of menopausal women. The findings of this study could be used

to inform healthcare practices and policies, particularly in India, where menopause-related health concerns are often under-recognised and under-treated. Moreover, the study could contribute to the global body of knowledge on menopause management and the role of physical exercise in promoting better health outcomes for women during this phase of life.

The ultimate goal of this research is to offer a solution that can help menopausal women lead healthier, more active, and fulfilling lives. By focusing on structured exercise programs as a means of improving quality of life, this study will offer a cost-effective, sustainable, and culturally relevant approach to managing menopause symptoms and promoting better health outcomes. If proven effective, the findings could lead to broader implementation of exercise interventions for menopausal women across India and other countries with similar socio-cultural contexts. This would be a significant step towards improving the overall health and quality of life of menopausal women globally.

1.2 Need of the Study

The need for this study stems from the increasing recognition of menopause as a significant life stage that can affect the overall well-being of women. Menopause is often a time when women experience substantial changes in their health, both physically and emotionally. In India, the number of women entering menopause is steadily rising, due to the increasing life expectancy and the fact that women are living longer lives[2]. This demographic shift presents a growing challenge for healthcare systems, which must adapt to the needs of an ageing population. As the number of postmenopausal women increases, it is essential to identify effective strategies to improve their quality of life and address the health concerns associated with this phase.

In many cultures, including Indian society, menopause has often been viewed as a taboo subject. Women going through this phase often do so without sufficient education, awareness,

or support, which can lead to a decline in their mental health and overall quality of life. The lack of public awareness and open discussion about menopause results in a gap in healthcare provision for women undergoing this transition. Moreover, many women in India, particularly those from rural or semi-urban areas, may face limited access to healthcare services that can help manage the symptoms of menopause. These women may not have adequate access to professional advice or appropriate treatments to alleviate menopausal discomforts, such as hormone replacement therapy (HRT), which can be expensive and less accessible in certain regions[9].

Structured exercise programs, however, offer a feasible, cost-effective, and easily accessible intervention that can improve the physical, psychological, and emotional well-being of menopausal women. There is growing evidence that physical activity, particularly structured exercise, can alleviate common menopausal symptoms such as hot flashes, sleep disturbances, and mood swings, while also improving bone density, cardiovascular health, and body composition. Regular exercise can also enhance self-esteem and boost energy levels, which are often negatively affected by the hormonal changes that occur during menopause[3].

While there is a wealth of research supporting the benefits of exercise for menopausal women, there is still limited evidence regarding the specific impact of structured exercise programmes in India, particularly in semi-urban settings like Bhopal. Cultural factors, lifestyle differences, and the socio-economic challenges faced by women in this region may result in unique barriers and opportunities for promoting exercise as a way of improving health outcomes during menopause. Therefore, conducting a randomised controlled trial (RCT) on the effect of structured exercise programmes on the quality of life among menopausal women in Bhopal is necessary to fill this knowledge gap.

Furthermore, an RCT is considered the gold standard for clinical trials and is crucial for producing reliable evidence about the effectiveness of interventions. By comparing an experimental group participating in a structured exercise program with a control group, this study will offer valuable insights into the causal relationship between exercise and quality of life outcomes. The results of this study could potentially guide future health interventions for menopausal women, not only in Bhopal but also in similar communities across India and other parts of the world.

This study will also contribute to the broader field of women's health by providing evidence that can be used to influence health policies and healthcare strategies aimed at menopausal women. Given the increasing burden of menopause-related health issues, the findings of this study could help inform public health initiatives and lead to the incorporation of structured exercise programmes into standard healthcare practices for menopausal women in India. By promoting exercise as a simple yet effective method of improving quality of life, this study could have a long-lasting impact on the health and well-being of menopausal women, empowering them to lead active, healthy, and fulfilling lives.

In conclusion, the need for this study is driven by the lack of sufficient evidence on the effects of structured exercise programs on the quality of life of menopausal women, particularly in the context of India. By addressing this gap in the literature, the study aims to provide valuable insights into the potential benefits of exercise for improving the physical and mental health of women undergoing menopause. The findings could serve as a basis for developing effective interventions to enhance the quality of life of menopausal women, ultimately contributing to better health outcomes for this growing population.

1.3 Research Problem Statement

"Effect of structured exercise program on quality of life among menopausal women in selected areas of Bhopal: A randomised controlled trial."

1.4 Research Questions

- What is the effect of a structured exercise program on the quality of life among menopausal women in selected areas of Bhopal?
- Does participation in a structured exercise program lead to a reduction in the physical symptoms (e.g., hot flashes, night sweats, joint pain) experienced by menopausal women?
- Are there any differences in quality of life based on various sociodemographic factors among menopausal women?

1.5 Objectives

- To assess the existing quality of life among menopausal women.
- To compare the quality of life between the exercise group (following structured exercise) and a control group (following routine activities).
- To determine the association between selected sociodemographic variables and the quality of life among menopausal women.

1.6 Operational definition

Effect: it refers to the extent to which structured exercise program has an impact on the quality of life among menopausal women, as assessed by differences in pre and post Quality of Life scores

Structured exercise program: A structured exercise program refers to a planned and systematic set of physical activities designed to improve physical fitness, mental well-being,

and overall health. In this study, the program consists of continuous, rhythmic movements that engage large muscle groups like walking, jogging, aerobic exercises and balance training, all scheduled over a period of 6 weeks. The program is supervised, with sessions taking place four times a week, each lasting 40 minutes to 1 hour.

Quality of life: Quality of life refers to an individual's overall well-being and satisfaction with various life domains, such as physical health, psychological state, social relationships, and environmental factors. In this study, quality of life is assessed using a validated instrument such as the *Menopause-Specific Quality of Life (MENQOL)* questionnaire, which evaluates domains like vasomotor symptoms (e.g., hot flashes, night sweats), physical functioning, emotional well-being, sexual health, and sleep disturbances. QOL is measured at baseline (before the intervention) and after 6 weeks of the structured exercise program.

Menopausal women: In this study refers to women who have reached the stage of menopause, which is characterised by the cessation of menstruation for 12 consecutive months confirmed through self-reporting or medical verification, such as clinical records.

1.7 Research hypothesis

H0: There is no significant difference in the quality-of-life scores between the exercise group and the control group of menopausal women.

1.8 Delimitation

This study is delimited to selected areas of Bhopal.

1.9 Conceptual Framework

The conceptual framework for this study is developed using a blend of relevant health and nursing theories that provide a foundation for understanding the complex relationships between exercise, quality of life, and the menopausal transition. The framework integrates concepts from **Roy's Adaptation Model**, **Pender's Health Promotion Model**, and **Theories of**

Quality of Life to explore how structured exercise programs can impact the physical, emotional, and psychological well-being of menopausal women.

Roy's Adaptation Model (RAM) is based on the premise that individuals adapt to environmental stimuli through physical, psychological, and social mechanisms. Menopause, as a natural biological process, often introduces significant physical and psychological challenges. According to RAM, health is seen as a process of adaptation to these changes, where interventions, such as structured exercise programs, help improve the adaptive response to menopause. In this framework:

- **Stimuli (Menopausal Transition):** The physical and psychological symptoms of menopause (e.g., hot flashes, night sweats, mood swings, insomnia) act as stimuli that disrupt a woman's adaptive equilibrium.
- **Coping Mechanisms (Exercise):** Exercise, as an adaptive coping mechanism, helps the body and mind respond positively to the changes occurring during menopause.
- **Outcome (Improved Quality of Life):** Through physical activity, menopausal women may experience improved physical health (e.g., reduced symptoms, enhanced fitness) and emotional well-being (e.g., reduced anxiety and depression), leading to a better quality of life.

The **goal** of this framework is to guide the intervention (exercise program) in helping menopausal women adapt more effectively to the physical and psychological changes associated with menopause, ultimately improving their quality of life.

Pender's Health Promotion Model focuses on promoting healthy behaviours and improving overall health through individual perceptions and behaviours. It emphasizes the role of personal beliefs, social support, and environmental factors in influencing health-promoting activities.

- **Perceived Benefits of Exercise:** According to Pender's model, the perceived benefits of exercise (e.g., improved mood, better sleep, enhanced physical fitness) are likely to motivate menopausal women to participate in the structured exercise program.
- **Perceived Barriers to Exercise:** Factors such as time constraints, social norms, and health conditions may act as barriers to engaging in the exercise program. Identifying and addressing these barriers is essential for promoting participation.
- **Social Support and Health Promotion:** Social support from family, friends, or healthcare providers plays a key role in encouraging adherence to the exercise program. In this study, support networks may be assessed to understand their role in influencing the success of the intervention.
- **Interpersonal and Environmental Factors:** The study will consider how environmental factors (e.g., accessibility of facilities) and interpersonal factors (e.g., relationships with family, healthcare professionals) influence the participants' engagement in the exercise program and their resulting quality of life.

By applying Pender's model, this study highlights how structured exercise can be promoted as a health-enhancing behaviour, helping menopausal women make lasting lifestyle changes that improve their overall health.

Quality of Life (QOL) theories emphasize that an individual's well-being is influenced by their ability to meet basic physical, psychological, and social needs. These theories suggest that QOL is multi-dimensional, and changes in one domain can have a ripple effect on others.

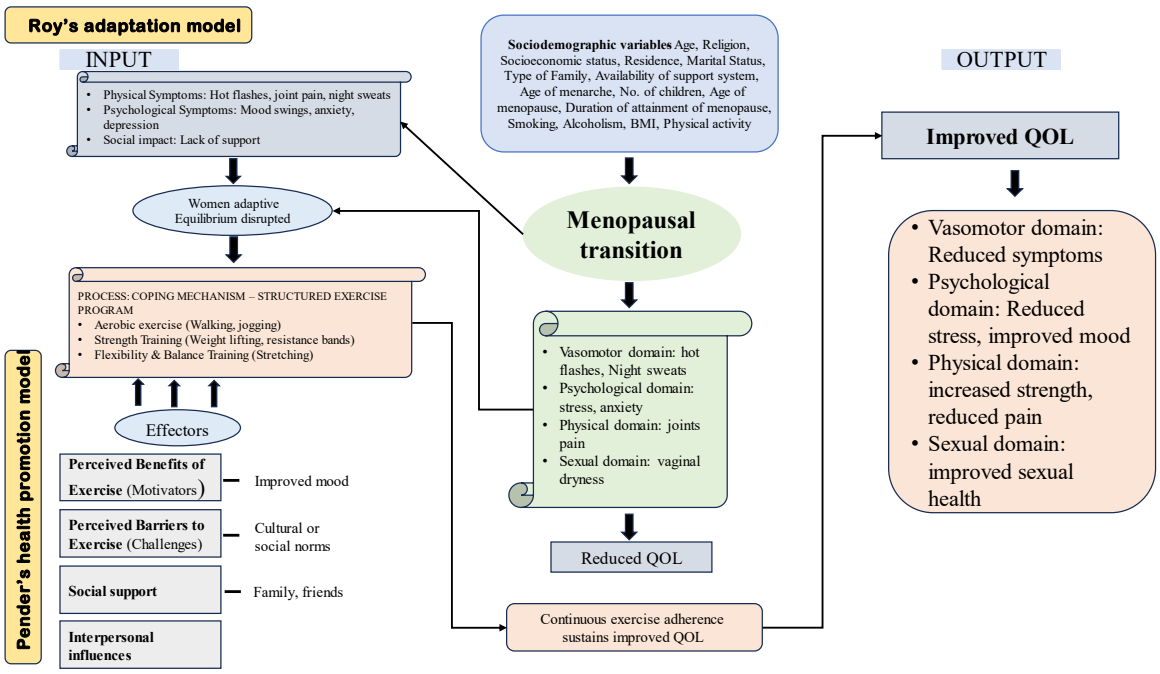
- **Physical Domain:** Physical health, such as the reduction of menopausal symptoms (e.g., hot flashes, joint pain), physical fitness, and increased energy levels, is a key element in enhancing quality of life.

- **Psychological Domain:** The psychological domain focuses on mood, stress levels, mental well-being, and emotional health. A structured exercise program can reduce anxiety, depression, and stress, leading to a more positive emotional state.
- **Social Domain:** Social relationships and overall engagement in life can improve with regular exercise, as it enhances confidence and emotional health, leading to more active social interactions.

This study integrates these domains by assessing how exercise influences multiple facets of quality of life, aiming for holistic improvements in physical, psychological, and social well-being.

Fig. 1 Conceptual Framework Diagram

The conceptual framework can be represented visually as follows:


Roy's adaptation model
INPUT
Physical Symptoms: Hot flashes, joint pain, night sweats
Psychological Symptoms: Mood swings, anxiety, depression
Social impact: Lack of support
Women adaptive Equilibrium disrupted
PROCESS: COPING MECHANISM – STRUCTURED EXERCISE PROGRAM
Aerobic exercise (Walking, jogging)
Strength Training (Weight lifting, resistance bands)
Flexibility & Balance Training (Stretching)
Effectors
Pender's health promotion model
Perceived Benefits of Exercise (Motivators)
Improved mood
Perceived Barriers to Exercise (Challenges)
Cultural or social norms
Social support
Family, friends
Interpersonal influences
Sociodemographic variables Age, Religion, Socioeconomic status, Residence, Marital Status, Type of Family, Availability of support system, Age of menarche, No. of children, Age of menopause, Duration of attainment of menopause, Smoking, Alcoholism, BMI, Physical activity
Menopausal transition
Vasomotor domain: hot flashes, Night sweats
Psychological domain: stress, anxiety
Physical domain: joints pain
Sexual domain: vaginal dryness
Reduced QOL
Continuous exercise adherence sustains improved QOL
OUTPUT
Improved QOL
Vasomotor domain: Reduced symptoms
Psychological domain: Reduced stress, improved mood
Physical domain: increased strength, reduced pain
Sexual domain: improved sexual health

1. **Menopausal Transition**: The onset of menopause introduces various physical and psychological changes. These changes, if not managed properly, can lead to a reduced quality of life.

2. **Roy's Adaptation Model**: Menopausal women, facing these changes, will need to adapt through mechanisms such as physical activity (exercise). Exercise acts as a positive adaptive response, helping to alleviate symptoms like hot flashes, joint pain, and mood swings.
3. **Structured Exercise Program**: The intervention in this study (structured exercise program) is designed to help menopausal women adapt better to these changes. It is expected that regular physical activity will enhance physical fitness, mental well-being, and emotional stability.
4. **Health Promotion**: Drawing on Pender's model, the study considers how individual perceptions (perceived benefits of exercise) and external factors (barriers to exercise and social support) influence the likelihood of engaging in and benefiting from the exercise program.
5. **Improved Quality of Life**: The ultimate goal is to improve the quality of life of menopausal women by enhancing physical, psychological, and social well-being. Structured exercise is expected to have a positive effect across these dimensions, leading to better overall health and life satisfaction.

The conceptual framework for this study integrates theories of adaptation, health promotion, and quality of life to explore how structured exercise can positively impact menopausal women's overall health and well-being. By focusing on exercise as a coping mechanism for menopause-related symptoms, this study aims to improve quality of life through a holistic approach that addresses physical, emotional, and social health.

Summary:

This chapter provided an overview of the study, outlining the background, need for the research, objectives, operational definitions, and the conceptual framework. It highlighted the impact of menopause on women's quality of life (QOL) and the potential benefits of structured exercise programs in improving physical, psychological, and emotional well-being. The study's focus was on assessing the effect of such a program on menopausal women in Bhopal. The conceptual framework, incorporating Roy's Adaptation Model and Pender's Health Promotion Model, laid the foundation for understanding the factors influencing QOL and exercise adherence, emphasizing the significance of this research in addressing menopausal health concerns.

CHAPTER II

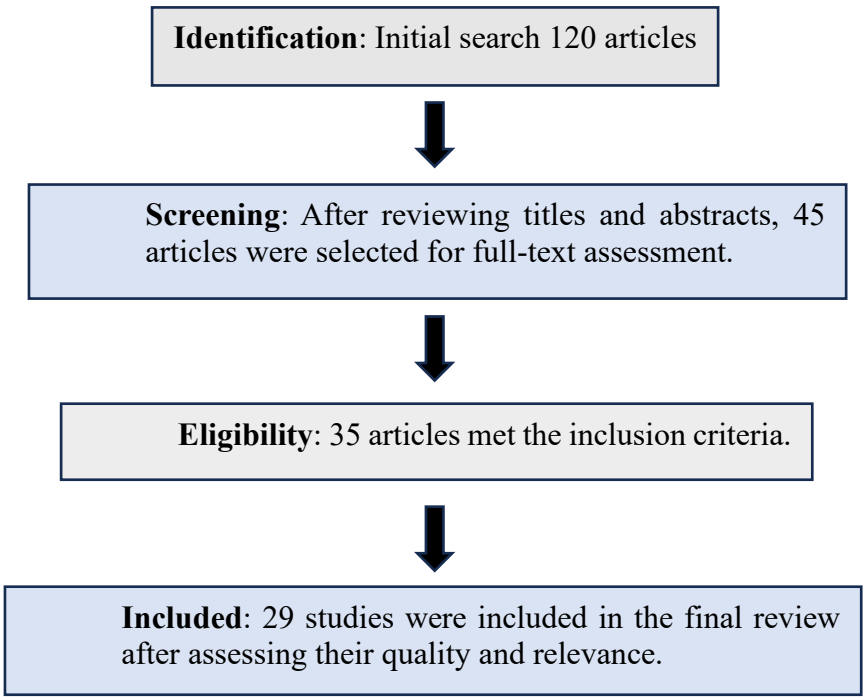
REVIEW OF LITERATURE

A literature review is systematically conducted to gain a thorough understanding of the research problem and identify gaps in existing studies, highlighting the need for further research. It assesses previous studies, evaluates methodologies, and synthesises findings to provide a conceptual framework and guide the research design. This chapter provides a comprehensive review of the existing literature on menopause, its impact on quality of life (QOL), and the role of structured exercise programs in mitigating these effects. The review begins with an overview of the physical, psychological, and social challenges faced by menopausal women, followed by an exploration of exercise as an intervention. The literature is organised into key sections, each addressing different aspects of menopause and exercise, helping to identify areas for further investigation and contributing to the advancement of knowledge in the field.

Search Strategy

The search strategy for this literature review followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines to ensure a systematic and comprehensive approach. Relevant studies were identified by searching multiple databases, including PubMed, Scopus, and Google Scholar. Boolean operators and MeSH (Medical Subject Headings) terms were used to refine the search. The search terms included “menopause,” “quality of life,” “exercise,” “structured exercise program,” “physical activity,” and “India.” Boolean operators such as AND, OR, and NOT were employed to combine these terms effectively (e.g., "menopause" AND "quality of life" AND "exercise" AND "India"). Only peer-reviewed articles published within the last twenty years were included, ensuring the inclusion of the most current research. Articles were selected based on their relevance to the research question, focusing particularly on those that examined the impact of exercise on

menopause-related symptoms and quality of life. Studies that discussed the effects of structured exercise programs on menopausal women were prioritised. A total of 120 studies were initially identified, and after screening for relevance, quality, and methodological rigor, 20 studies were included in the final review. This approach ensured a comprehensive collection of relevant, high-quality studies that address the research question.


Identification: Initial search 120 articles
Screening: After reviewing titles and abstracts, 45 articles were selected for full-text assessment.
Eligibility: 35 articles met the inclusion criteria.
Included: 29 studies were included in the final review after assessing their quality and relevance.

The literature review is organised under the following headings:

1. **Menopause and Its Impact.**
2. **Quality of Life in Menopausal Women**
3. **Tools to assess Quality of Life in Menopausal Women**
4. **Interventions to Improve Quality of Life in Menopausal Women**
5. **Structured Exercise and Quality of Life**

2.1 Menopause and Its Impact on Women's Life

Menopause marks a significant phase in a woman's life, defined by the cessation of menstruation for twelve consecutive months. It generally occurs between the ages of forty five and fifty five though this can vary based on individual health, genetics, and environmental factors. The transition to menopause, often referred to as perimenopause, is accompanied by a wide array of physical, psychological, and social changes that can significantly affect a woman's quality of life. Physically, women experience a range of symptoms including hot flashes, night sweats, and sleep disturbances, which can lead to fatigue and reduced daily functioning. These symptoms are a result of hormonal fluctuations, primarily the decrease in oestrogen levels, and can persist for several years. In addition to vasomotor symptoms, women may also experience joint pain, headaches, and weight gain, all of which can negatively affect physical well-being[8]. Furthermore, menopause is associated with an increased risk of long-term health conditions, such as osteoporosis and cardiovascular disease.

The psychological impacts of menopause are equally significant. Women often report increased mood swings, irritability, anxiety, and depressive symptoms during this transition. The hormonal changes can contribute to emotional instability, and many women experience feelings of loss related to aging, fertility, and changes in body image. For some, menopause can feel isolating, particularly when cultural taboos or a lack of awareness prevent open discussions about the experience Socially, women may face challenges in maintaining active relationships or engaging in social activities, exacerbating feelings of loneliness and reduced life satisfaction[6].

2.2 Quality of Life in menopausal Women

Quality of life (QOL) is a multidimensional concept that encompasses physical, emotional, social, and psychological well-being (World Health Organization, 1997). In postmenopausal women, QOL can be significantly affected by the symptoms associated with menopause, such as vasomotor issues, sleep disturbances, and changes in mental health. Studies indicate that women's QOL decreases during menopause due to these symptoms, and this decline can continue into the postmenopausal years.

Research has shown that the physical impacts of menopause, such as weight gain, joint pain, and osteoporosis, can contribute to decreased mobility, affecting women's ability to perform daily tasks. Furthermore, the psychological burden, particularly anxiety and depression, can impact mental health and overall life satisfaction[11]. Social isolation is also a key factor affecting QOL, with some studies suggesting that menopausal women experience a reduction in social participation and activities due to physical discomforts and mood disorders. Additionally, postmenopausal women report significant challenges in adapting to the new identity and role within society, as menopause is often framed negatively in many cultures. The concept of QOL in postmenopausal women has been explored through various measurement tools, such as the Menopause-Specific Quality of Life (MENQOL) questionnaire, which assesses physical, psychological, and sexual health[29]. Studies using these tools indicate that QOL improvements can be achieved through interventions such as lifestyle changes, exercise, and psychosocial support, highlighting the importance of addressing all facets of health during the postmenopausal transition.

2.3 Tools to Assess Menopausal Quality of Life (QOL)

Assessing the quality of life (QOL) of menopausal women is crucial for understanding the physical, emotional, and social challenges they face during this transition. Several tools have

been developed to measure QOL in menopausal women, each focusing on different dimensions of health and well-being. These tools enable researchers and clinicians to quantify the impact of menopausal symptoms and evaluate the effectiveness of interventions. Below are some of the most widely used tools for assessing QOL in menopausal women.

Menopause-Specific Quality of Life (MENQOL) Questionnaire

The MENQOL is one of the most widely used tools to assess QOL in menopausal women. It was developed by Hunter and colleagues in 2000 and is specifically designed to measure the impact of menopausal symptoms on women's daily lives (Hunter et al., 2000). The questionnaire includes items that assess four key domains: vasomotor symptoms (e.g., hot flashes, night sweats), physical symptoms (e.g., fatigue, joint pain), psychosocial symptoms (e.g., mood swings, depression), and sexual function (e.g., sexual desire, vaginal dryness). The MENQOL has been validated in numerous studies across different populations, making it a reliable tool for both clinical and research settings[8,29].

The questionnaire uses a Likert scale to assess the severity of symptoms, allowing for the identification of problem areas and changes over time (Lindh-Astrand et al., 2006). The MENQOL has been praised for its comprehensive approach, as it captures the multidimensional nature of menopausal QOL. It is particularly valuable for tracking symptom progression and evaluating the effectiveness of interventions like hormone therapy or exercise programs (Lindh-Astrand et al., 2006).

The Menopause Rating Scale (MRS) The Menopause Rating Scale (MRS) is another frequently used tool for evaluating the impact of menopause on QOL. It was developed by Heinemann et al. (2003) and focuses on assessing the severity of 11 physical and psychological symptoms that women commonly experience during menopause. These include vasomotor

symptoms, sleep disturbances, psychological symptoms (e.g., irritability, anxiety, depression), and physical symptoms (e.g., joint pain, fatigue).

The MRS provides a global score that allows for a quick assessment of menopausal symptoms and can be used to track symptom improvement or deterioration over time. Like the MENQOL, the MRS uses a Likert scale, but its focus on a smaller set of symptoms may make it easier to use in clinical settings where time is limited (Heinemann et al., 2003). Studies have shown that the MRS is a reliable and valid tool for assessing menopausal symptoms in both clinical trials and everyday clinical practice (Heinemann et al., 2003).

The Health-Related Quality of Life (HRQOL) Scale: The HRQOL scale is a broader tool used to measure QOL, not just during menopause but across a variety of health conditions. It assesses physical, mental, and social well-being, providing a holistic view of health. The HRQOL tool is often used in conjunction with other menopause-specific instruments to provide a more complete picture of a woman's overall health during the menopausal transition (Ware & Sherbourne, 1992).

In the context of menopause, the HRQOL scale can capture aspects of women’s health that are not directly related to specific menopausal symptoms, such as the impact of comorbid conditions or lifestyle factors on general well-being. While the HRQOL tool is less specific to menopause, it offers valuable insight into how menopause and other life factors interact to affect overall quality of life (Ware & Sherbourne, 1992).

The WHO Quality of Life (WHOQOL) Instrument: The WHOQOL instrument, developed by the World Health Organization (1998), is a comprehensive tool designed to assess general QOL across a range of health conditions. It includes questions related to physical health, psychological well-being, social relationships, and environmental factors. The WHOQOL

instrument has been adapted for use in diverse populations and settings, making it a valuable tool for cross-cultural comparisons of menopausal QOL (WHO, 1998).

While it is not menopause-specific, the WHOQOL instrument can provide important information on how menopause interacts with other life factors to affect a woman's overall well-being. This tool is particularly useful when researchers aim to compare the QOL of menopausal women with other groups or to assess the impact of menopause in a broader socio-cultural context (WHO, 1998).

The Sexual Function Questionnaire (SFQ) Sexual function is a key aspect of QOL that is often affected during menopause due to hormonal changes, vaginal dryness, and reduced libido. The Sexual Function Questionnaire (SFQ) is specifically designed to assess sexual health in women, including aspects such as sexual desire, arousal, orgasm, and satisfaction (Wiegel et al., 2005). In the context of menopause, the SFQ can be particularly valuable for understanding how menopausal symptoms impact sexual functioning, which is often a neglected aspect of QOL assessments. The SFQ has been used in various studies to evaluate the effects of interventions like hormone therapy, lubricants, and exercise on improving sexual function during menopause (Wiegel et al., 2005).

These tools, from the MENQOL to the WHOQOL, provide comprehensive assessments of menopausal QOL, each offering unique insights into different aspects of women's health. The selection of a tool depends on the research or clinical context, with some instruments focusing on specific symptoms (e.g., vasomotor, sexual function) and others providing a broader evaluation of general health. Using a combination of these tools allows for a more nuanced understanding of how menopause affects women’s lives, helping to guide clinical interventions and improve health outcomes.

2.4. Interventions to Improve Quality of Life in Menopausal Women

Given the range of physical and psychological challenges posed by menopause, multiple interventions have been suggested to improve the QOL of menopausal women. Pharmacological options, such as hormone replacement therapy (HRT), have long been used to alleviate vasomotor symptoms, but these treatments are not suitable for all women due to side effects or contraindications (Lumsden & Sood, 2017). Non-hormonal treatments, including selective serotonin reuptake inhibitors (SSRIs) and gabapentin, have also been shown to reduce hot flashes and improve mood (Lloyd et al., 2018). However, these medications often fail to address the holistic nature of menopause and may not be accessible or affordable in all regions.

Lifestyle modifications, including dietary changes, weight management, and physical activity, have emerged as promising interventions to improve QOL in menopausal women. Regular physical activity, particularly aerobic and strength training exercises, has been shown to alleviate many menopausal symptoms, such as hot flashes, fatigue, joint pain, and mood disturbances (Jancey et al., 2013). Exercise is also beneficial for bone health and the prevention of osteoporosis, which becomes a critical concern postmenopausal (DiPietro, 2019). Moreover, exercise is associated with improved mental health, enhancing self-esteem, reducing anxiety and depression, and promoting better sleep (Joffe et al., 2017).

Psychosocial interventions, such as counselling and support groups, have also been identified as effective in improving QOL for menopausal women (Berg & Miller, 2019). These interventions focus on providing emotional support, stress management techniques, and education about menopause, which can empower women to better manage their symptoms and improve their overall well-being.

2.5 Structured Exercise and Quality of Life

Among the various interventions, structured exercise programs have been widely studied for their potential to improve the QOL of menopausal women. These programs typically include aerobic exercises, strength training, flexibility routines, and balance exercises, each addressing specific aspects of physical health and well-being. Research has shown that regular participation in structured exercise programs can significantly reduce the frequency and severity of menopausal symptoms such as hot flashes, joint pain, and sleep disturbances (Collette et al., 2018).

In a study by Mikkelsen et al. (2019), women who participated in a structured exercise program experienced significant improvements in both physical and mental health, including reduced fatigue, better sleep quality, and enhanced mood. The benefits of exercise are believed to arise from its effects on hormone regulation, the reduction of body fat, and the enhancement of cardiovascular health (Trost et al., 2017). Additionally, exercise helps improve muscle strength and joint function, which is particularly important as menopausal women are at increased risk of musculoskeletal issues due to the decline in oestrogen levels.

The positive impact of structured exercise on mental health has also been widely documented. Regular physical activity has been found to reduce symptoms of anxiety and depression in menopausal women, likely due to the endorphin release and stress-reducing effects of exercise (Salvatore et al., 2019). Moreover, structured exercise provides social benefits, as it often involves group activities, which can reduce feelings of isolation and support social connections.

Physical activity has been shown to provide numerous benefits for menopausal women. Regular exercise improves cardiovascular health, strengthens bones, and helps manage weight—all of which are particularly crucial for women after menopause. Exercise has also been found to enhance mental well-being by reducing symptoms of anxiety, depression, and

improving sleep quality. For example, aerobic exercises such as walking, swimming, and cycling help improve heart health, while strength training exercises reduce the risk of osteoporosis by maintaining bone density. Flexibility exercises such as yoga and stretching can alleviate joint pain, which is a common issue for menopausal women.

Research Gap Analysis

What is Already Known:

Existing studies have consistently demonstrated that menopause significantly impacts the quality of life (QOL) of women, encompassing a range of physical, psychological, and social symptoms that negatively affect their overall well-being. Common symptoms include hot flashes, mood swings, sleep disturbances, and physical discomfort, all of which can reduce a woman's ability to function effectively in daily life. Research has shown that regular physical exercise can alleviate many of these symptoms, improving both physical and mental health outcomes. Specifically, exercise is associated with reductions in vasomotor symptoms, improved mood, enhanced sleep quality, and better physical fitness, which collectively contribute to a better QOL.

However, most of the research on exercise and menopause has predominantly focused on populations in Western countries, such as the United States and Europe, where access to healthcare and structured exercise programs is relatively more widespread. While these studies offer valuable insights, they may not be directly applicable to other regions, particularly in developing countries where socio-economic and cultural factors may present additional challenges to women's participation in such programs. Moreover, the impact of structured exercise programs on menopausal women in India remains underexplored. In India, where cultural norms, healthcare accessibility, and socio-economic barriers significantly influence

health behaviors, there is limited evidence regarding how structured physical activity programs can improve the QOL of menopausal women.

What This Research Adds:

This research addresses the existing gap by specifically focusing on the impact of structured exercise programs on menopausal women in Bhopal, India. The study seeks to explore how a culturally tailored exercise program can improve various dimensions of QOL during menopause, such as physical health, mental well-being, and social functioning. The findings from this research will provide valuable insights that can inform healthcare practices and policies in India, as well as in other regions with similar socio-cultural contexts.

One of the key contributions of this research is its focus on women in semi-urban and rural areas, where access to healthcare facilities and exercise programs is often limited. These women may face unique barriers, such as a lack of time, social support, or financial resources, which can affect their participation in structured physical activity programs. By addressing these specific challenges and developing culturally sensitive interventions, the study aims to generate practical solutions that can be implemented effectively in these settings. Furthermore, the research will add to the growing body of literature on the benefits of exercise for menopausal women, particularly in non-Western settings, thereby expanding the generalizability of findings beyond Western populations.

While there is a substantial body of research that demonstrates the benefits of exercise for menopausal women, a gap remains in understanding how structured exercise programs specifically impact the QOL of women from diverse cultural and socio-economic backgrounds. This research will fill this gap by evaluating the effectiveness of structured exercise programs for menopausal women in India, considering the socio-cultural and economic factors that may influence participation and outcomes. Ultimately, the study will contribute to a more holistic

understanding of exercise as an intervention for menopausal women in diverse settings, particularly in developing countries like India, where such programs may be less accessible.

SUMMARY

This chapter provides an in-depth literature review on the impact of menopause on women's quality of life (QOL), emphasizing the physical, psychological, and social challenges faced during this transition. It highlights the role of structured exercise programs in alleviating menopausal symptoms and improving QOL, with a particular focus on existing research from Western countries. However, a significant gap exists in understanding how such interventions specifically affect women in India, especially in semi-urban and rural areas where socio-cultural and economic barriers may hinder participation. The chapter outlines the need for this research to fill this gap, offering valuable insights into how culturally tailored, structured exercise programs can improve QOL for menopausal women in Bhopal, India, and similar regions.

CHAPTER III

MATERIALS AND METHODS

This chapter outlines the research methodology for the study titled "Effect of Structured Exercise Program on Quality of Life Among Menopausal Women in Selected Areas of Bhopal: A Randomized Controlled Trial." It provides a detailed description of the research approach, design, study setting, population, sample selection, data collection tools, and methods for data analysis.

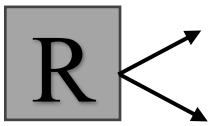
Research Approach

The study adopts a **True Experimental** research approach, which is designed to determine the cause-and-effect relationship between the independent variable (structured exercise program) and the dependent variable (quality of life among menopausal women). This approach ensures manipulation, control, and randomization, which are the key characteristics of a true experimental study.

Research Design

A **pre-test-post-test control group design** with randomization was used for this study. This design aims to assess the effect of a structured exercise program on the quality of life of menopausal women. Participants were randomly assigned to either the experimental group or the control group to observe the changes in their quality of life.

Fig 2: Schematic representation of research design



GROUP	PRE-TEST	INTERVENTION	POST-TEST
Experimental	P1	**X Structured exercise program**	P2
Control	P1	**Routine Activities**	P2

P1- pre test

X intervention – structured exercise program

P2- post test

Research setting

The research for this study was conducted in selected areas of Bhopal, India. These areas were chosen due to their accessibility and the presence of a diverse population of menopausal women, providing a representative sample for the study. The setting allowed for effective implementation of the structured exercise program and data collection from participants meeting the inclusion criteria.

Population

The target population for this study consisted of menopausal women in Bhopal. The accessible population was specifically menopausal women residing in a designated community within Bhopal. These women were selected based on the inclusion criteria to participate in the study.

Sample

The sample for this study consisted of menopausal women from Berkheda Pathani, community area in Bhopal who met the inclusion criteria. After identifying eligible participants, randomisation was carried out, and the women were assigned to either the experimental or control group.

Inclusion Criteria:

- Women aged between 45 and 60 years.
- Confirmed menopausal status, either through clinical diagnosis or self-reported symptoms.
- Willingness to actively participate in the study and provide informed consent.
- Residing in the selected community areas of Bhopal.

Exclusion Criteria:

- Presence of cardiovascular, musculoskeletal, or other chronic medical conditions that may contraindicate exercise.
- Current participation in any other structured physical exercise or fitness program.
- Medical conditions that pose risks or limit the ability to engage in physical activity as prescribed in the study.
- Women with severe psychiatric disorders or cognitive impairments that could affect their ability to comply with the study protocol.

Sample Size

The sample size for this study was determined to be 80 participants, divided into two groups: participants in the experimental group and 5participants in the control group. The sample size

was calculated based on a thorough review of relevant literature and power analysis to ensure adequate statistical power for detecting meaningful differences between the groups.

The formula used for sample size calculation is:

$n = 4\delta^2/E^2$

Where:

n = sample size per group

δ = the expected effect size (difference in means), $\delta = 0.7$

E = the margin of error or precision, E=0.221

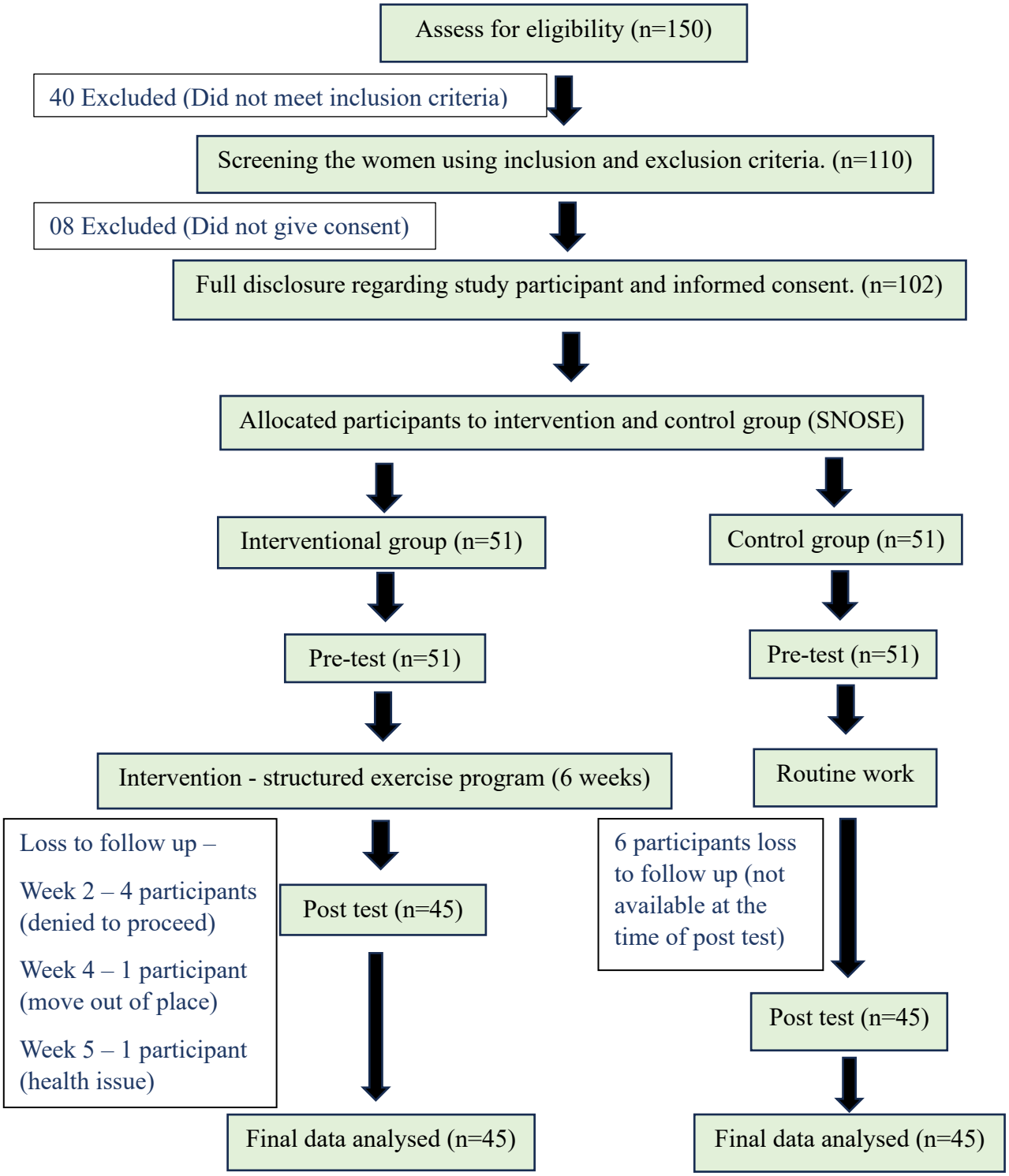
n = 40

Thus, recruiting 102 participants would ensure to achieve desired **sample size of 40** after accounting for a 10% attrition rate [8]. The sample recruitment process is shown in Figure 3. The final analyzed sample included 45 participants in each group.

Sampling technique

The sampling technique used in this study was simple random sampling, followed by randomization with a 1:1 allocation. To ensure unbiased group assignment, sequentially numbered opaque sealed envelopes (SNOSE) were employed for the randomization process. This method facilitated the random distribution of participants into either the experimental or control group. Initially, participants were selected through convenient sampling, and then the randomization process was applied to allocate them to the respective groups.

Fig.3 CONSORT Flow Diagram for Participant Recruitment


Assess for eligibility (n=150)
40 Excluded (Did not meet inclusion criteria)
Screening the women using inclusion and exclusion criteria. (n=110)
08 Excluded (Did not give consent)
Full disclosure regarding study participant and informed consent. (n=102)
Allocated participants to intervention and control group (SNOSE)
Interventional group (n=51)
Control group (n=51)
Pre-test (n=51)
Pre-test (n=51)
Intervention - structured exercise program (6 weeks)
Routine work
Loss to follow up –
Week 2 – 4 participants (denied to proceed)
Week 4 – 1 participant (move out of place)
Week 5 – 1 participant (health issue)
Post test (n=45)
6 participants loss to follow up (not available at the time of post test)
Post test (n=45)
Final data analysed (n=45)
Final data analysed (n=45)

Data collection tools and techniques

Data collection is a critical component of research as it provides the essential information required to answer the research questions. The accuracy and quality of the data collected are largely determined by the tools used for gathering the data. In this study, the data collection tools were designed and developed to align with the study objectives, ensuring they were suitable and relevant for assessing the effects of a structured exercise program on the quality of life of menopausal women.

Development of the Tool

The data collection tools for this study were carefully designed by the researcher, drawing from existing literature and expert advice to ensure that the tools accurately captured relevant information regarding the quality of life of menopausal women and the impact of structured exercise. The following steps were involved in the development process:

Literature Review: A thorough review of existing literature was conducted, focusing on studies related to menopause, quality of life, and the role of structured exercise programs in improving physical and psychological well-being during menopause. This literature review helped identify the key variables to measure and guided the design of the data collection instruments.

Drafting the Research Instrument: The initial version of the research tools was developed, including questions to assess the sociodemographic characteristics of the participants and their quality of life before and after the intervention. The tools were designed to capture both the baseline data on menopausal symptoms and the impact of the structured exercise program on various domains of quality of life.

Consultations and Feedback: After developing the first draft, the tool was reviewed through consultations with experts in the fields of gynecology, exercise science, and public health.

Feedback was solicited from the study's guide, co-guide, and other specialists. The experts provided valuable insights regarding the content, structure, and language of the tool. Based on their suggestions, revisions were made to improve the clarity and relevance of the tool. Additionally, a Content Validity Index (CVI) was calculated to assess the content validity of the tool.

Finalizing the Tool: Following consultations and revisions, the final version of the tool was prepared. It was reviewed to ensure it addressed all necessary domains related to the research objectives and was capable of effectively measuring the quality of life and the impact of exercise. The finalized tool was made ready for data collection.

Ethical Approval: Before data collection commenced, ethical approval was sought and obtained from the institutional ethical review board. The ethical approval process ensured that the study adhered to ethical guidelines, protecting participants' rights, confidentiality, and well-being throughout the research process.

Description of the Tools

The following tools were used in this study to collect relevant data:

1. **Sociodemographic Data Sheet**: A self-structured questionnaire was used to gather basic sociodemographic information about the participants, such as age, marital status, education level, occupation, family income, type of family, and dietary habits. This information was essential for understanding the characteristics of the sample population and any potential confounding factors.
2. **Menopause-Specific Quality of Life (MENQOL) Questionnaire**: The MENQOL questionnaire was the primary instrument used to assess the quality of life of menopausal women. This tool measures the impact of menopausal symptoms across four domains: vasomotor symptoms, psychosocial symptoms, physical symptoms, and

sexual symptoms. The MENQOL consists of 29 items, each rated on a Likert scale, with higher scores indicating a greater negative impact on quality of life. The MENQOL was chosen due to its proven reliability and validity in assessing menopausal quality of life.

3. **Structured Exercise Program Assessment**: This tool was used to assess the type, frequency, and intensity of the exercise program that participants followed. It ensured that the structured exercise program adhered to the planned intervention and captured participant engagement and adherence to the program.

4. **Follow-Up Questionnaire**: At the end of the intervention, a follow-up questionnaire was administered to assess the perceived benefits and challenges of participating in the structured exercise program. This questionnaire also included questions on participant satisfaction and overall experience.

Data Collection Tools

The data collection tools for this study included a sociodemographic data sheet and the Menopause-Specific Quality of Life (MENQOL) questionnaire, which assessed the impact of menopausal symptoms on various aspects of life. These tools were designed to capture both baseline and post-intervention data, allowing for an evaluation of the effect of a structured exercise program on the quality of life of menopausal women.

Part A: Socio-demographic Data Sheet A self-structured socio-demographic data sheet was used to collect information on variables such as age, marital status, education, occupation, family income, residence, type of family, and dietary patterns.

Part B: Menopause-Specific Quality of Life (MENQOL) Questionnaire

The **MENQOL** questionnaire is a widely recognized tool for measuring the quality of life in menopausal women developed by **Hilditch et al.** in **1996** [Annexure 3]. It consists of 29 items, and respondents rate the impact of menopausal symptoms on different aspects of their life using a Likert scale. The questionnaire covers four specific domains:

1. **Vasomotor Symptoms** (3 items) – Hot flashes, night sweats
2. **Psychosocial Symptoms** (7 items) – Mood, anxiety, and psychological well-being
3. **Physical Symptoms** (16 items) – Joint and muscle pain, fatigue, sleep disturbances
4. **Sexual Symptoms** (3 items) – Impact of menopause on sexual function

Each item is rated on a scale from 1 to 8, where 1 indicates no symptoms and 8 indicates the most bothersome symptoms. A higher score reflects a poorer quality of life. Score of 29-80 shows no decline, 81-131 indicates mild decline, 132-182 indicates moderate decline and 183-232 indicates severe decline in QOL among menopausal women.

Validity and Reliability of the Tools

Validity

The validity of the tools used in this study was ensured through both face and content validity assessments. Face validity was established through discussions with the guide and co-guide to ensure the tool's relevance and clarity. Content validity was evaluated using the Scale Content Validity Index (SCVI) based on the average method and the universal agreement (UA) method. The background proforma, a self-structured tool, was developed after reviewing the literature and reviewed by a panel of ten experts in fields such as Nursing, Community Medicine, Obstetrics & Gynecology, and Community Health Nursing. Expert feedback was incorporated to assess the relevance of each item. The tool was also translated into Hindi and back-translated

into English by a bilingual expert to ensure linguistic accuracy. Based on the feedback, modifications were made, and the final tool was confirmed with the guide and co-guide. The Scale Content Validity Index (SCVI) for the final tools was as follows: SCVI (average method) = 0.98, SCVI (UA method) = 0.99. The MENQOL scale used in this study is a standardized tool, and the Cronbach's alpha for the MENQOL was reported at 0.90, indicating high internal consistency.

Reliability

The reliability of the tools was assessed by applying Cronbach's alpha to a sample of 12 menopausal women. The results showed that the tools demonstrated acceptable to very good reliability. The MENQOL tool had a Cronbach's alpha of 0.90, indicating strong internal consistency. The reliability of the data collection instruments was thus confirmed, ensuring their ability to yield consistent results across different samples and settings.

The MENQOL tool was reviewed for content validity by ten experts in relevant fields, and its language was validated by Hindi language experts. The tool demonstrated a high internal consistency of **0.90**, confirming its reliability.

Ethical Considerations

The research proposal was submitted to the institutional ethics committee, and approval was granted to conduct the study. Ethical approval for the study was granted by the Institutional Human Ethical Committee-Student Research at AIIMS Bhopal (Ref No.: IHEC-SR/2024/109, dated 1st February 2024). This RCT was registered in the Clinical Trials Registry- India (**CTRI**) and the registration number is CTRI/2024/04/066223. Informed consent was obtained from all participants, ensuring they were fully aware of the study's purpose, objectives, and potential benefits. Participants' confidentiality was ensured throughout the study. Permission was also obtained from the Chief medical officer of the Urban PHC for conducting the study.

Pilot Study

After obtaining ethical approval, a pilot study was conducted to assess the feasibility of the main study. This pilot study was carried out among 10 participants, which represented 10% of the intended sample size, from 28th June 2024 to 10th August 2024. The study was conducted in Berkheda Pathani, Bhopal. The pilot study followed the same objectives, data collection procedures, and analysis techniques as outlined in the Letter of Permission (LOP) for the main study. The pilot study provided valuable insights into the feasibility of the larger study and highlighted potential challenges. Based on the results, the pilot study confirmed that the main study could proceed as planned.

Data Collection Procedure

The main investigation aimed to achieve the objectives outlined in the current study. After obtaining ethical clearance and necessary permissions from relevant authorities, data collection commenced from 15th August 2024 to 18th August 2024 for pre test. All menopausal women meeting the inclusion and exclusion criteria were enrolled. Participants were thoroughly informed about the study, including its objectives, potential benefits, and any risks involved. Informed written consent was obtained from all participants.

Data collection involved conducting one-on-one interviews, where participants were asked to provide information related to socio-demographic tool and MENQOL Questionaire.

Each session lasted approximately 25–30 minutes, during which participants provided details about their sociodemographic characteristics, problems related to health they are facing as per the questions of MENQOL Questionanire. After that intervention administered to the interventional group.

Table 3.1 Follow up of participants of interventional group

Weeks	No. of participants in intervention group	Reason to loss to follow up
Week 1	51	
Week 2	47	4 participants loss to follow up (Denied to proceed)
Week 3	47	
Week 4	46	1 participants loss to follow up (move out of place)
Week 5	45	1 participant loss to follow up (Health issue)
Week 6	45	

After 6 weeks of intervention post test taken from both groups.

Intervention Details: The structured exercise program comprised 40-minute sessions, conducted four days a week, focusing on:

Warm-up (5 minutes): Gentle stretching and mobility exercises

- Marching in Place: 2 minutes (Start with a gentle march in place, gradually lifting knees higher and swinging arms).
- Arm Circles: 1 minute (Extend arms to the sides and perform small circles forward for 30 seconds, then backward for 30 seconds).

- Leg Swings: 1 minute (Swing one leg forward and backward, then switch legs. Repeat for 30 seconds on each leg).

- Neck and Shoulder Rolls: 1 minute (Roll shoulders forward and backward for 30 seconds, followed by gentle neck rolls in both directions).

Flexibility and Balance (5 minutes): Stretching and balance exercises

- Standing Hamstring Stretch: 2 minute (Keep the leg straight, and lean forward gently. Hold for 30 seconds, then repeat).
- Standing Side Stretch: 3 minute (Stand with feet shoulder-width apart. Reach one arm overhead and lean to the opposite side. Hold for 30 seconds on each side).

Aerobic Exercise (15 minutes): Brisk walking, step-touch movements, and light dance.

- Brisk Walking or Light Jogging in Place: 5 minutes (Encourage a steady pace, focused on maintaining a comfortable but challenging intensity).
- Step Touch with Arm Movements: 5 minutes (Step to the right and bring the left foot to meet it, then step to the left and bring the right foot to meet it).
- Low-Impact Dance Movements: 5 minutes (Incorporate simple dance moves to upbeat music, such as side steps, grapevines, or light twists, to keep the session fun and engaging).

Strength Training (10 minutes): Bodyweight squats, leg lifts, bicep curls, and calf raises.

- Bodyweight Squats: 3 minutes (Perform squats with feet shoulder-width apart, lowering down, then returning to standing. Aim for 3 sets of 10-15 repetitions).
- Standing Leg Lifts: 3 minutes (Lift one leg to the side, keeping it straight, then lower it back down. Repeat on the other side. Aim for 3 sets of 10-15 repetitions per leg).

- Bicep Curls: 2 minutes (Hold weights or resistance bands in each hand, with arms extended down. Curl the weights towards the shoulders, then lower slowly. Aim for 2 sets of 10-15 repetitions).
- Calf Raises: 2 minutes (Stand with feet hip-width apart. Raise your heels off the ground to stand on your toes, then slowly lower back down. Aim for 2 sets of 15-20 repetitions).

Cool-down and Relaxation (5 minutes): Deep breathing and standing meditation.

- Deep Breathing Exercises: 2 minutes (Inhale deeply through the nose, hold for a few seconds, and exhale slowly through the mouth. Repeat this breathing pattern to relax the body and mind).
- Standing Meditation: 3 minutes (Close your eyes, focus on your breath, and release any remaining tension in the body. Encourage positive thoughts and a sense of calmness).

Data Analysis Plan

Data was analyzed using both **descriptive** and **inferential statistics**. Descriptive statistics such as percentages and frequencies were used to summarize the data, while inferential statistics, including the **Wilcoxon Signed Rank Test** and **Mann Whitney U Test**, were used to analyze pre and post-test differences. Data analysis was carried out using **MS Excel** and **SPSS** software.

Summary

This chapter outlined the research methodology for the study on the effect of a structured exercise program on the quality of life of menopausal women in Bhopal. It covered the research design, sample selection, data collection tools, ethical considerations, and the data analysis plan. The next chapter will present the analysis and interpretation of the data.

CHAPTER IV

RESULT

This chapter presents the results of the study on the "Effect of a structured exercise program on the quality of life among menopausal women in selected areas of Bhopal: A randomized controlled trial." The findings are presented in relation to the research questions and objectives outlined earlier. Statistical analyses were conducted to evaluate the impact of the exercise intervention on the quality of life of menopausal women and its relationship with sociodemographic variables.

According to Polit and Hungler, data analysis is a structured process that entails organizing and interpreting data to answer research questions and evaluate hypotheses. In this study, both descriptive and inferential statistics were applied to organize, examine, and interpret the data in line with the study's main objectives. The collected data was carefully analyzed using MS Excel 365 and IBM SPSS Statistics (Version 22), ensuring that the analysis was consistent with the study's predetermined goals.

Organization and presentation of the findings- The presentation of the study findings is systematically structured to provide a clear and comprehensive understanding of the research outcomes. The following sections highlight the key elements of the data analysis process and the results, ensuring a logical flow that addresses the study's objectives and research questions.

Section I: Sociodemographic Characteristics of the Sample: This section outlines the sociodemographic profile of the study participants, including variables such as age, marital status, education level, and employment status. Descriptive statistics like frequencies, percentages, and means are used to summarize this data for both the intervention and control groups.

Section II: Pre and post-intervention menopausal quality of life among menopausal women. This section presents an assessment of the quality of life in both the intervention and control groups both prior to the intervention and after the intervention, using mean scores, standard deviation, frequency, and percentage

Section III: Comparative Analysis of Quality of Life Between Intervention and Control Groups: This section compares the quality of life between the interventional and control groups after the intervention using the MENQOL questionnaire. Statistical tests such as the Wilcoxon Signed-Rank Test and the Mann-Whitney U Test are applied to analyze any significant differences between the two groups.

Section IV: Association Between Sociodemographic Variables and Menopausal Quality of Life: This section examines the association between selected sociodemographic variables and the quality of life among menopausal women.

SECTION I: SOCIODEMOGRAPHIC CHARACTERISTICS OF THE SAMPLE

The study included 90 menopausal women who were randomly assigned to either the interventional group (structured exercise program) or the control group (routine activities). The sociodemographic characteristics of the participants were analyzed to explore how various factors might influence the study outcomes. The findings are summarized in the Annexure 13. The data shows no significant differences between the two groups for most variables, with p-values for all variables greater than 0.05, indicating homogeneity in the sociodemographic characteristics of both groups. Notably, there were small variations in age distribution, marital status, support systems, and lifestyle factors, but these differences were not statistically significant.

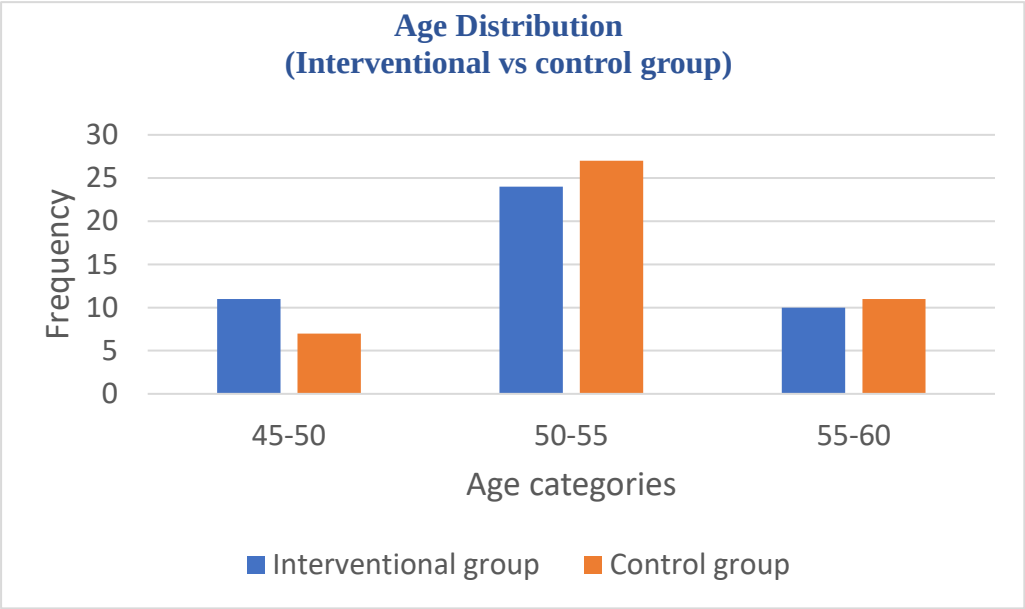


Fig. 4.1: Age distribution of Menopausal women

Most of the participants belong to 50-55 category of age group(24(53.3%) (in interventional group and 27(60%) in control group)

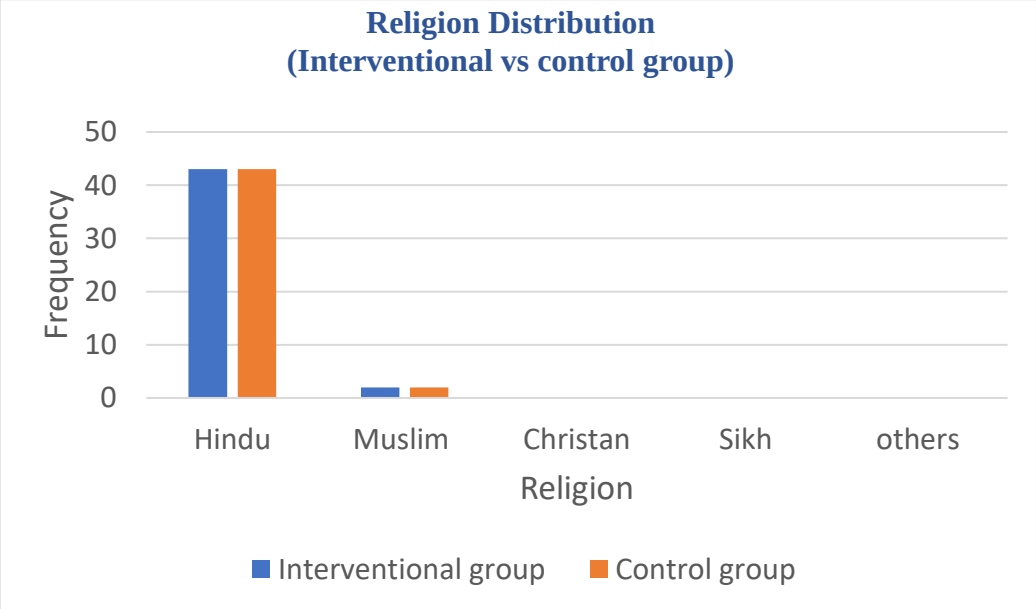


Fig. 4.2: Religion distribution of Menopausal women

Equal no. of participants belong to Hindu and Muslim Religion (43 Hindu in both groups and 2 Muslim in both groups)

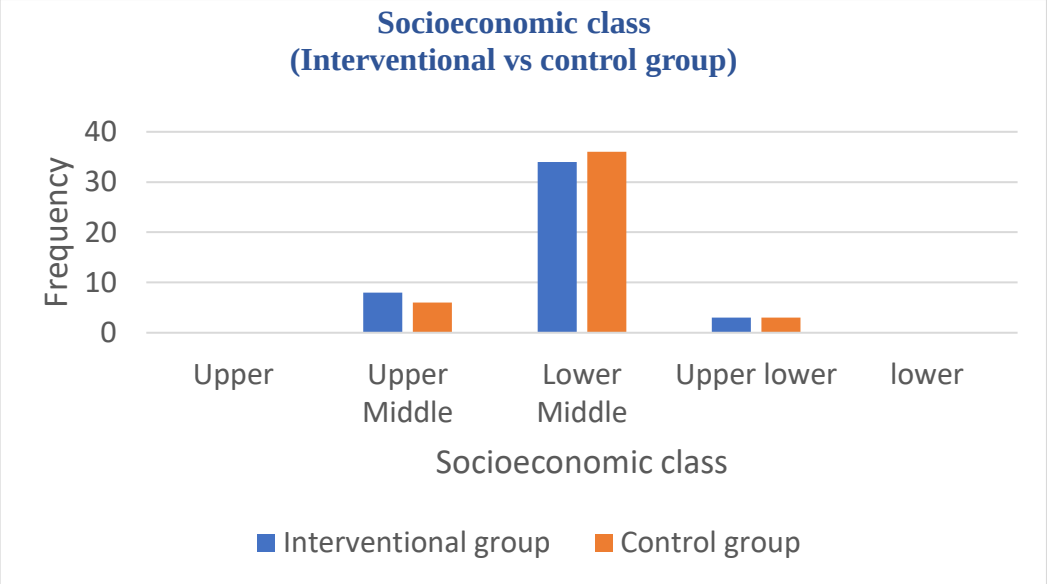


Fig. 4.3: Socioeconomic distribution of Menopausal women

Most of participants belongs to lower middle socioeconomic class {34 (75.6%) in interventional group and 36 in control group (80%)}

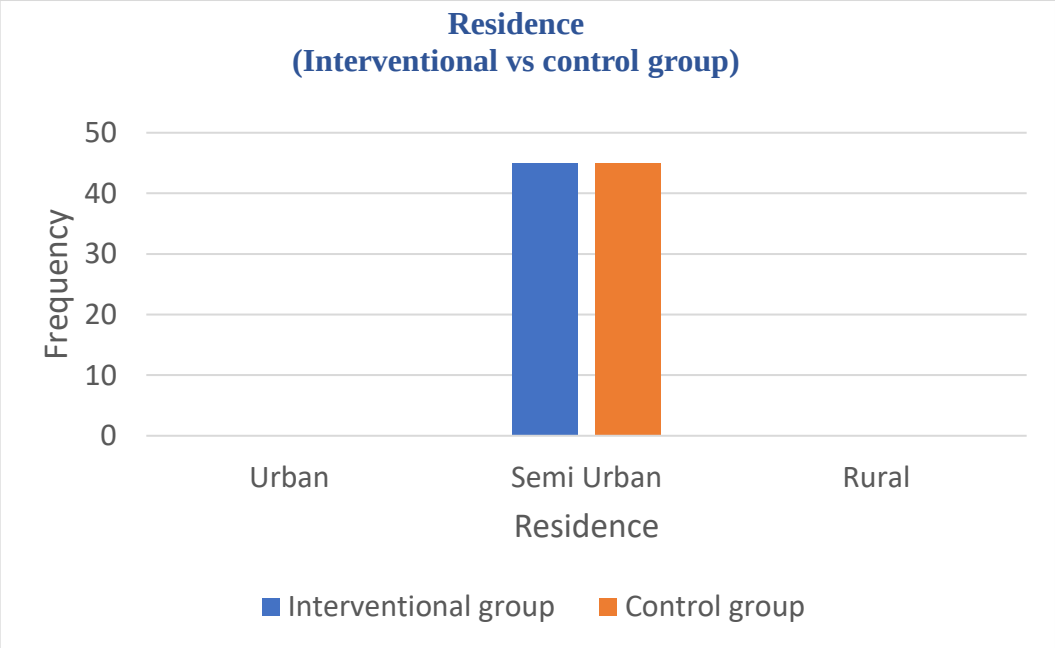


Fig. 4.4: Residence distribution of Menopausal women

All participants belong to semi urban residence

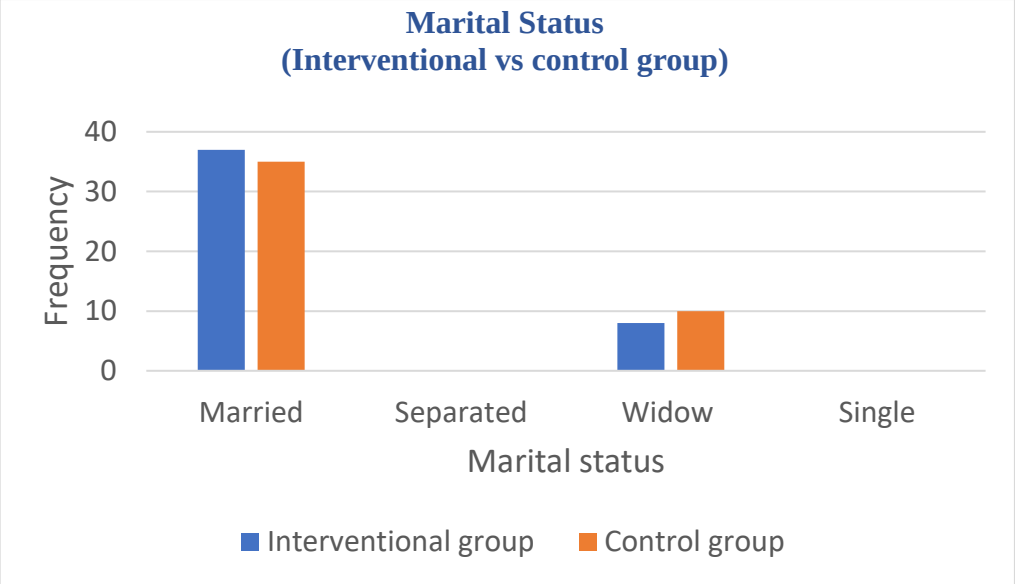


Fig. 4.5: Distribution of Menopausal women as per Marital status

Most of the participants are married in both groups {37(82.2%) in interventional group and 35(77.8%) in control group}

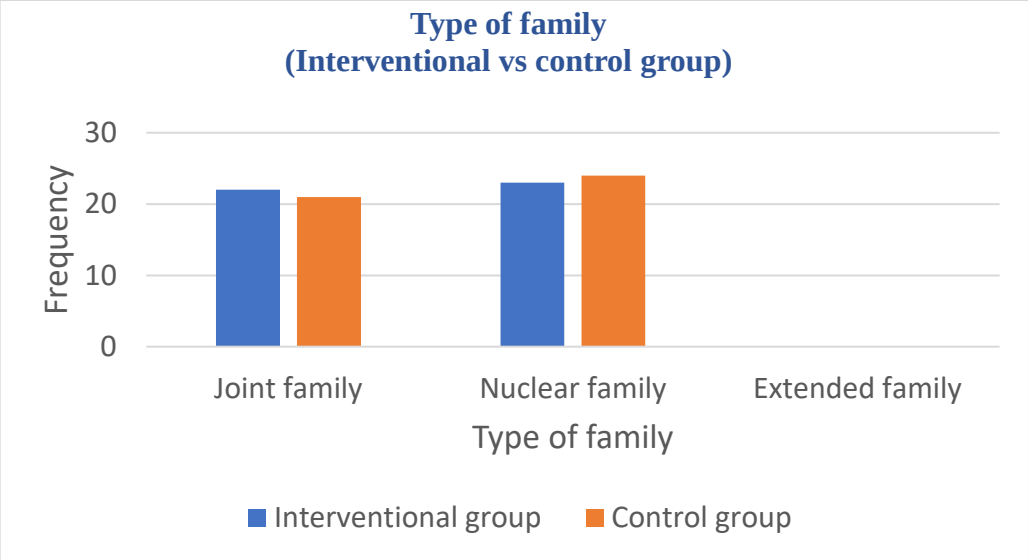


Fig. 4.6: Distribution of Menopausal women as per type of family

Most of the participants belongs to nuclear family in both groups {23(51.1%) in interventional group and 24(53.3%) in control group}

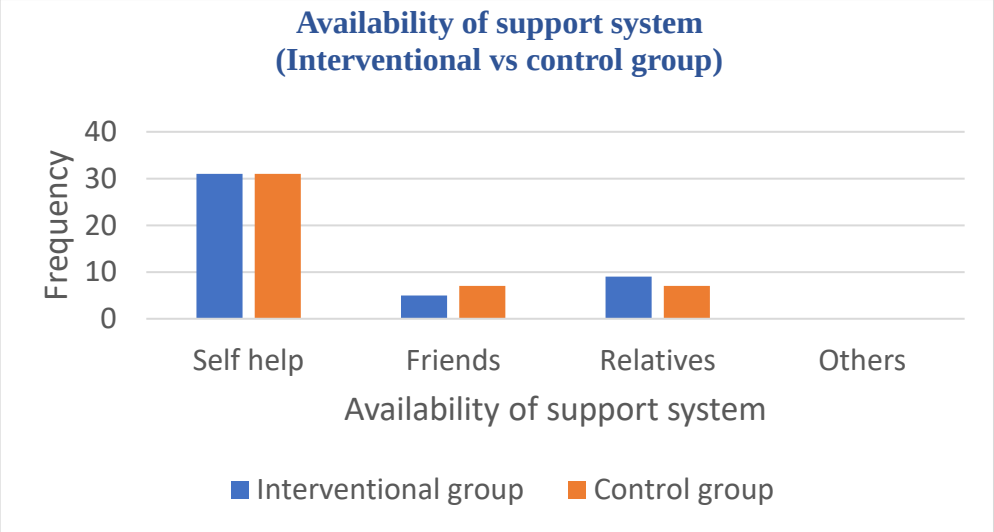


Fig. 4.7: Availability of support system among Menopausal women

Most of the participants belongs to self help in both groups {31(68.9%) in interventional group and 31(68.9%) in control group}

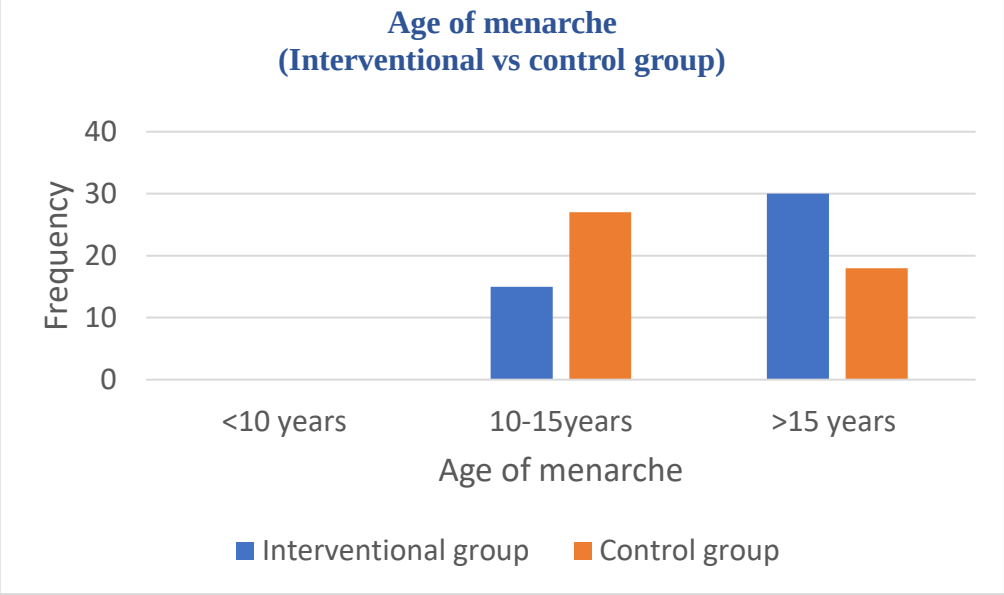


Fig. 4.8: Age of menarche among Menopausal women

Age of Menarche in most of participants of interventional group more than 15 years {30 (66.7%)} and in control group between 10-15 years {27(60%)}

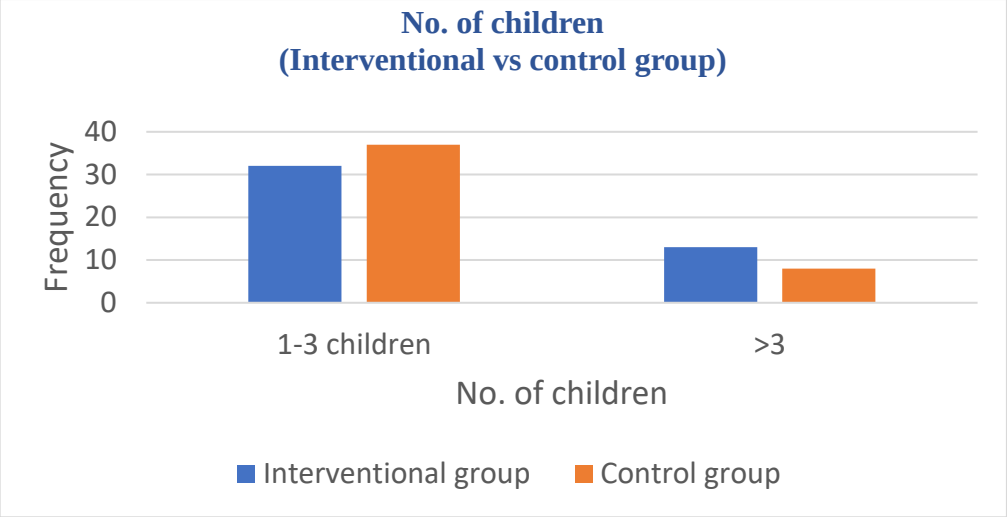


Fig. 4.9: No. of children among Menopausal women

Most of the participants have 1-3 children in both groups {33(71.1%) in the interventional group and 37(82.2%) in control group}

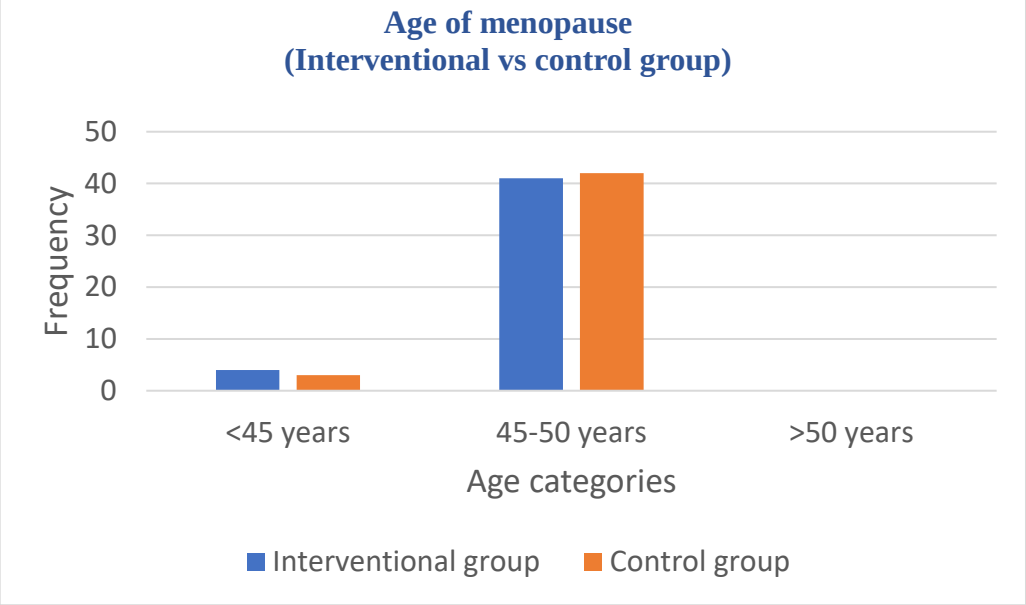


Fig. 4.10: Age of Menopause among Menopausal women

Age of menopause in most of the participants is between 45-50years in both groups {41(91.1%) in the interventional group and {42(93.3%) in control group}

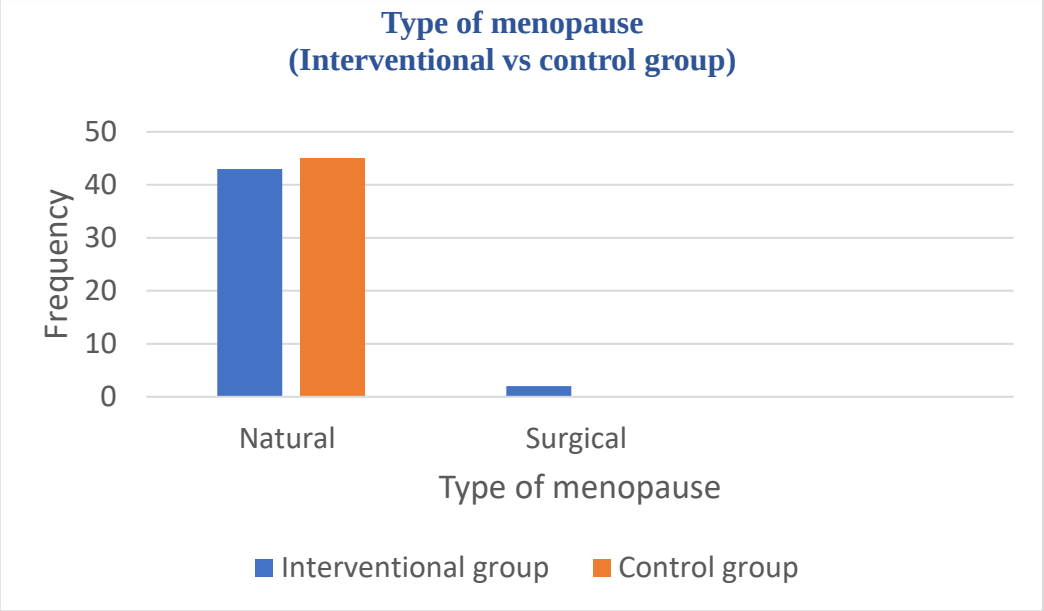


Fig. 4.11: Type of menopause among Menopausal women

Most of the participants have natural menopause in both groups {43(95.6%) in the interventional group and 45(100%) in control group}

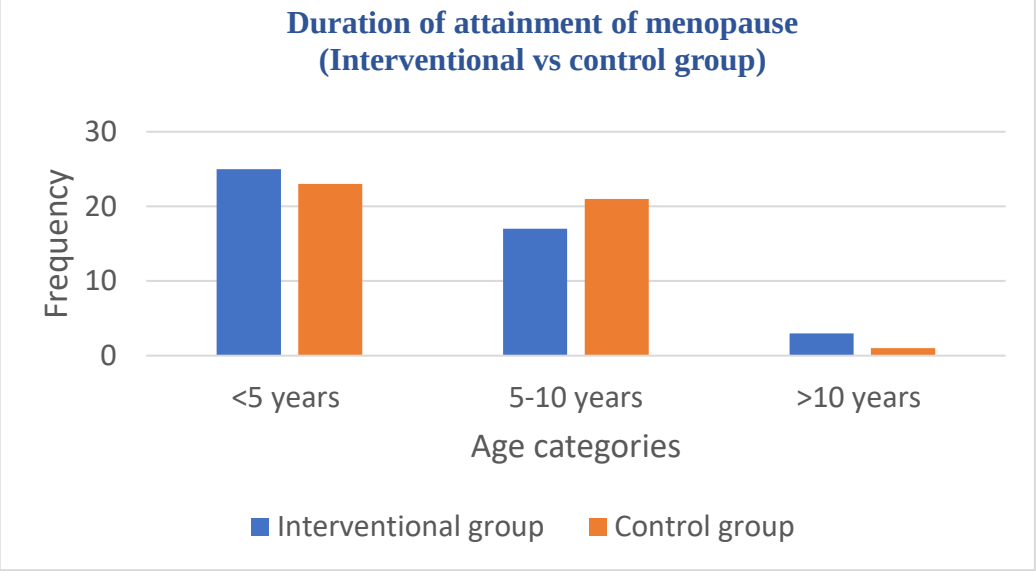


Fig. 4.12: Duration of attainment of menopause among Menopausal women

Most of the participants belongs to category less than 5 years of attainment of menopause in both groups {25(55.6%) in the interventional group and 23(51.1%) in control group}

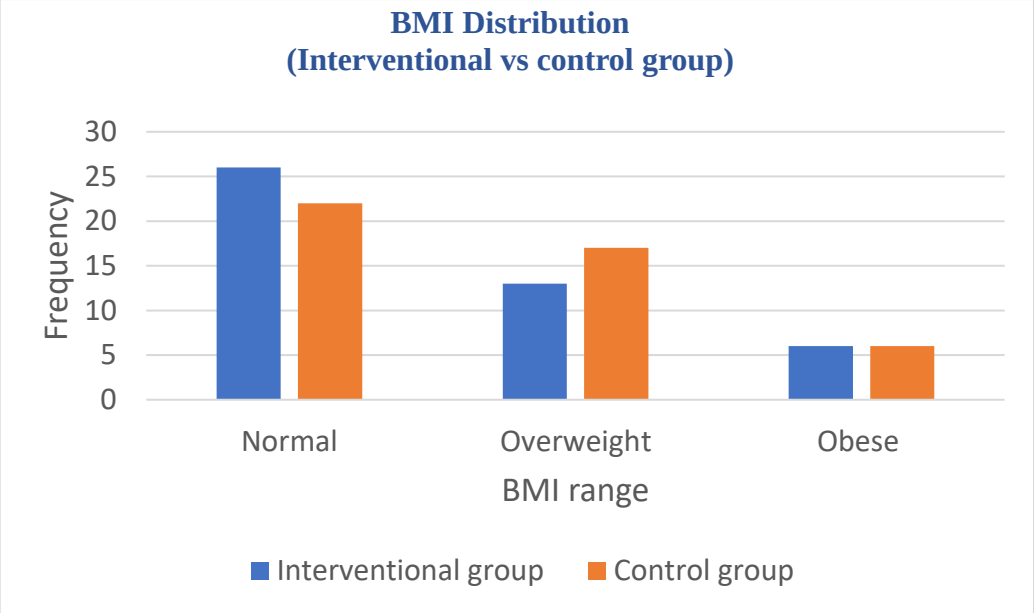


Fig. 4.13: BMI distribution among Menopausal women

Most of the participants have normal BMI in both groups {26(57.8%) in the interventional group and 22(48.9%) in control group}

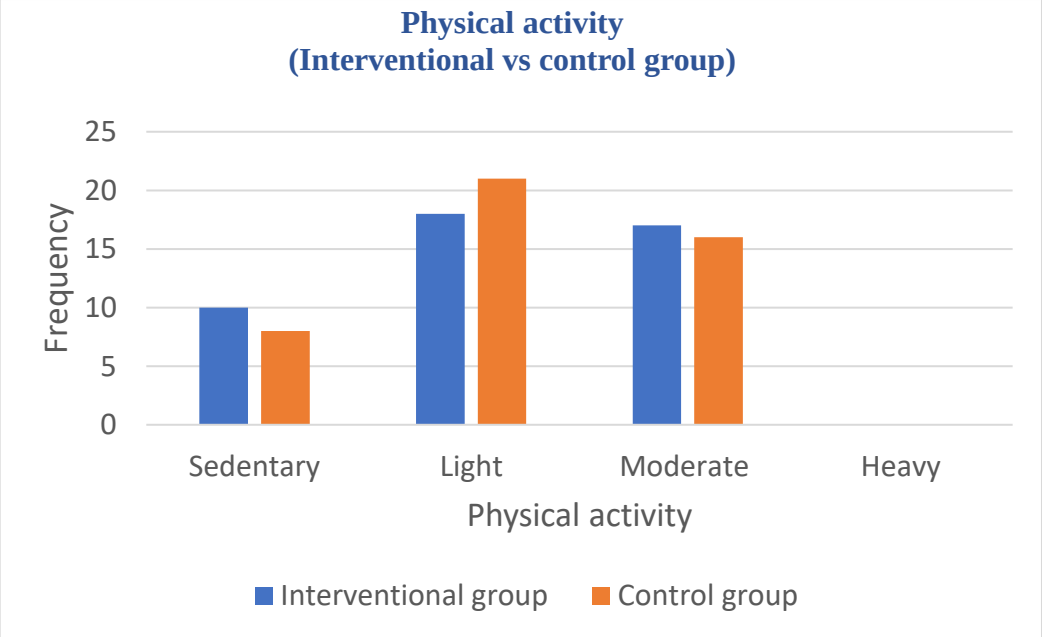


Fig. 4.14: Physical activity among Menopausal women

Most of the participants have light physical activity in both groups {18(40%) in the interventional group and 21(46.7%) in control group}

SECTION II: PRE AND POST INTERVENTION MENOPAUSAL QUALITY OF LIFE AMONG MENOPAUSAL WOMEN

Table 4.1 Illustrates the distribution of Quality of Life (QOL) scores for both the intervention and control groups before and after the intervention.

Pre-intervention : In the intervention group, 7% (3 women) reported no decline in QOL, 53% (24 women) experienced mild decline, and 40% (18 women) reported moderate decline. The mean QOL score for the intervention group was 121.8 (SD ±22.54). Whereas in the control group, 11% (5 women) reported no decline, 60% (27 women) had mild decline, and 29% (13 women) experienced moderate decline. The mean QOL score for the control group was 117.9 (SD ±22.8).

Post-intervention: The intervention group showed a dramatic improvement, with 98% (44 women) reporting no decline in QOL. Only 2% (1 woman) had a mild decline. The mean QOL score significantly improved to 57.96 (SD ±12.48).Furthermore the control group showed no significant change, with 11% (5 women) still reporting no decline, 60% (27 women) experiencing mild decline, and 29% (13 women) having moderate decline. The mean QOL score remained almost unchanged at 117.7 (SD ±23.1).

To sum up the intervention group demonstrated a significant improvement in their QOL post-intervention, with most women experiencing no decline in their scores. In contrast, the control group showed minimal to no change in their QOL scores from pre- to post-intervention.

Table 4.1: Pre and Post Intervention Menopausal Quality of Life In Intervention and Control Groups

Quality of life	Pre intervention						Post intervention					
	Interventional group (N=45)			Control group (N=45)			Interventional group (N=45)			Control group (N=45)		
	f (%)	Mean	SD	f (%)	Mean	SD	f (%)	Mean	SD	f (%)	Mean	SD
No decline (29 – 80)	**3(7%)**	66.6	±14.97	**5 (11%)**	70.2	±10.0	**44 (98%)**	56.6	±8.9	**5 (11%)**	69.0	±10.3
Mild decline (81 – 131)	**24(53%)**	115.3	±15.16	**27 (60%)**	116.4	±13.35	**1 (2%)**	116.0	-	**27 (60%)**	116.4	±13.3
Moderate decline (132 – 182)	**18(40%)**	139.9	±6.76	**13(29)**	139.38	±5.82	**0**	-	-	**13 (29%)**	139.3	±5.8
Severe decline (183 – 232)	**0**	-	-	-	-	-	**0**		-	**0**		
Overall		**121.8**	±22.54		**117.9**	±22.8		**57.96**	±12.48		**117.7**	±23.1

NORMALITY OF DATA

The normality of the data was evaluated using the Kolmogorov-Smirnov test (K-S test) and the Shapiro-Wilk test through SPSS prior to selecting the suitable statistical test.

Variable	K-S test	S-W test
QOL	0.000	0.000

P value < 0.05, so that the data collected was not normally distributed.

The results of both the Kolmogorov-Smirnov (K-S) test and the Shapiro-Wilk (S-W) test for Quality of Life (QOL) show a p-value of 0.000 for each test. Since the p-value is less

than the set p value of 0.05, it indicates that the data do not follow a normal distribution. Therefore, non-parametric statistical methods should be used for further analysis

TESTING OF HYPOTHESIS

To evaluate the significance of differences in Menopausal Quality of Life (MENQOL) between the intervention and control groups, the following null hypothesis was formulated at a 0.05 level of significance:

H0: There is no significant difference in the menopausal quality of life scores between the intervention group and the control group of menopausal women.

SECTION III: EFFECTIVENESS OF STRUCTURED EXERCISE PROGRAM ON MENOPAUSAL QUALITY OF LIFE (QOL)

The Wilcoxon Signed-Rank Test and Mann-Whitney U test were used to determine significant differences in menopausal Quality of Life (QOL) scores within the groups and between the groups, respectively.

Table no 4.2 Within group comparison of menopausal quality of life

Group	p-value	Standardized Test Statistic (Z)	Positive differences	Negative differences	Number of Ties
Interventional Group (n=45)	0.000 (S)	-5.842	0	45	0
Control Group (n=45)	0.063 (NS)	-1.857	0	4	41

Within-Group Comparison of Menopausal Quality of Life

The Wilcoxon Signed-Rank Test was performed to assess the significance of changes in QOL scores within both the intervention and control groups before and after the intervention. The p-value for the intervention group is 0.000, which is less than the significance level of 0.05, indicating a statistically significant improvement in QOL scores from pre- to post-intervention. The negative test statistic (Z = -5.842) suggests that all participants in the intervention group experienced an improvement in their QOL. There were no positive differences, meaning all 45 participants showed a negative change in scores, confirming an overall positive effect. The p-value for the control group is 0.063, which is greater than 0.05, indicating no statistically significant difference in QOL scores from pre- to post-intervention. The test statistic (Z = -1.857) is not large enough to suggest a significant change. Only 4 participants showed a negative change in QOL, with the remaining 41 participants showing no change (ties).The above results show that the intervention group experienced a significant improvement in QOL, whereas the control group did not show any significant change.

Between-Group Comparison of Menopausal Quality of Life

The Mann-Whitney U test was used to compare the differences in QOL scores between the intervention and control groups before and after the intervention.

Pre-intervention: The mean rank for the intervention group is 48.10, while the mean rank for the control group is 42.90. The p-value for the pre-intervention comparison is 0.344, which is greater than the significance level of 0.05. This indicates no statistically significant difference in QOL scores between the intervention and control groups before the intervention.

Post-intervention: The mean rank for the intervention group is 24.24, whereas the mean rank for the control group is 46.76. The p-value for the post-intervention comparison is 0.000, which is less than 0.05, indicating a statistically significant difference between the two groups. The intervention group showed a significantly greater improvement in QOL scores compared to the control group.

While there was no significant difference in QOL scores between the groups before the intervention, significant differences were seen in QOL between groups after the intervention.

Table no 4.3 Between group comparison of menopausal quality of life

Group	Mean ranks	Mann-Whitney U Test	p value	Mean ranks	Mann-Whitney U Test	p value
	Pre intervention			Post intervention		
Interventional group (n=45)	48.10	895.5	0.344 (NS)	24.24	1969	0.000 (S)
Control group (n=45)	42.90			46.76		

From the analysis, it is clear that the calculated p-value is less than the significance level ($p < 0.05$) for both the within-group comparison for the intervention group and the between-group comparison after the intervention. However, there was no significant difference within the control group ($p = 0.063$). Therefore, the null hypothesis is rejected, and the research hypothesis is supported at the 0.05 significance level. It can be concluded that the structured exercise program is effective in improving the menopausal quality of life among menopausal women**.**

SECTION IV: ASSOCIATION BETWEEN SOCIODEMOGRAPHIC VARIABLES AND MENOPAUSAL QUALITY OF LIFE

This section presents the findings related to the association between sociodemographic variables and menopausal Quality of Life (QOL) among menopausal women. The Chi-square test was used to assess these associations.

Table no 4.4. Association of Sociodemographic Variables with Menopausal QOL Among Menopausal Women (N=90)

S. No	Variables	Menopausal QOL			Chi-square Value	df	p-value
		No decline	Mild decline	Moderate decline			
1.	Age (in years)						
	45-50	2	11	5	6.81	4	0.14 (NS)
	50-55	2	32	16			
	55-60	4	8	10			
2.	Religion						
	Hindu	8	47	31	3.20	2	0.20 (NS)
	Muslim	0	4	0			
3.	Socio economic class						
	Upper middle	0	9	5	7.82	4	0.98 (NS)
	Lower middle	6	38	26			
	Upper lower	2	4	0			
4.	Marital status						
	Married	7	46	19	10.37	2	0.006 (S)
	Widow	1	5	12			
5.	Type of family						
	Joint	3	25	15	0.37	2	0.82 (NS)
	Nuclear	5	26	16			
6.	Availability of support system						
	Self help	5	36	21	7.35	4	0.11 (NS)
	Friends	3	7	2			
	Relatives	0	8	8			
7.	Age of menarche						
	10-15 yrs	2	34	21	5.56	2	0.06 (NS)
	> 15 yrs	6	17	10			
8.	No. of children						
	1-3	6	38	25	0.41	2	0.81 (NS)
	>3	2	13	6			
9.	Age of menopause						

	<45 yrs	1	6	0	3.99	2	0.13 (NS)
	45-50 yrs	7	45	31			
10.	Type of menopause						
	Natural	7	50	31	4.61	2	0.10 (NS)
	Surgical	1	1	0			
11.	Duration of attainment of menopause, years						
	<5	4	25	19	10.51	4	0.03 (S)
	5-10	2	24	12			
	>10	2	2	0			
12.	Do you smoke?						
	No	8	50	31	0.77	2	0.67 (NS)
	Yes	0	1	0			
13.	Do you consume alcohol?						
	No	8	51	31	Constant		
14.	BMI						
	Normal	6	24	18	4.00	4	0.40 (NS)
	Overweight	1	21	8			
	Obese	1	6	5			
15.	Physical activity						
	Sedentary	0	12	6	5.38	4	0.25 (NS)
	Light	4	18	17			
	Moderate	4	21	8			

S= p-value significant at 0.05 level of significance.

NS = p-value not significant at 0.05 level of significance

The above table depicts that factors such as age, religion, socio-economic class, type of family, and age of menopause did not have significant associations with QOL, as indicated by p-values greater than 0.05 (NS). However, marital status ($p = 0.006$), duration of attainment of menopause ($p = 0.03$), and smoking status ($p = 0.67$) showed significant relationships with QOL. Specifically, married women had better QOL compared to widows, and those who had attained menopause for a longer period experienced better QOL. The analysis suggests that certain sociodemographic factors, such as marital status and duration of menopause, significantly influence the menopausal QOL, while others like age, religion, and type of family do not.

Table no 4.5: Domain-wise Frequency and Percentage of Symptoms Experienced by Women Prior to Intervention (N=45)

S.No.	Domain	Item	No		Yes	
			frequency	Percentage (%)	frequency	Percentage (%)
1.	Vasomotor	Hot flashes or flashes	11	24.4	34	75.6
2.		Night sweats	8	17.8	37	82.2
3.		Sweating	2	4.4	43	95.6
4.	Psychosocia	Being dissatisfied with my personal life	15	33.3	30	66.7
5.		Feeling anxious or nervous	7	15.6	38	84.4
6.		Experiencing poor memory	4	8.9	41	91.1
7.		Accomplishing less than I used to	5	11.1	40	88.9
8.		Feeling depressed, down, or blue	1	2.2	44	97.8
9.		Being impatient with other people	21	46.7	24	53.3
10.		Feeling of wanting to be alone	33	73.3	12	26.7
11.		Flatulence (wind) or gas pains	1	2.2	44	97.8
12.		Aching in muscles and joints	3	6.7	42	93.3
13.		Feeling tired or worn out	3	6.7	42	93.3
14.		Difficulty sleeping	0	0	45	100
15.		Aches in back of neck or head	2	4.4	43	95.6
16.		Decrease in physical strength	0	0	45	100

17.	Physical	Decrease in stamina	8	17.8	37	82.2
18.		Feeling a lack of energy	1	2.2	44	97.8
19.		Drying skin	4	8.9	41	91.1
20.		Weight gain	23	51.1	22	48.9
21.		Increased facial hair	23	51.1	22	48.9
22.		Changes in appearance, texture or tone of your skin	4	8.9	41	91.1
23.		Feeling bloated	0	0	45	100
24.		Low backache	2	4.4	43	95.6
25.		Frequent urination	32	71.1	13	28.9
26.		Involuntary urination when laughing or coughing	40	88.9	5	11.1
27.	Sexual	Change in your sexual desire	0	0	45	100
28.		Vaginal dryness during intercourse	0	0	45	100
29.		Avoiding intimacy	0	0	45	100

Table 4.6 Domain-wise Frequency and Percentage of Symptoms Experienced by Women Post Intervention (N=45)

S.No.	Domain	Item	No		Yes	
			frequency	Percentage (%)	frequency	Percentage (%)
1.	Vasomotor	Hot flashes or flashes	23	51.1	22	48.9
2.		Night sweats	19	42.2	26	57.8
3.		Sweating	4	8.9	41	91.1
4.		Being dissatisfied with my personal life	16	35.6	29	64.4

5.	Psychosocia	Feeling anxious or nervous	22	48.9	23	51.1
6.		Experiencing poor memory	11	24.4	34	75.6
7.		Accomplishing less than I used to	10	22.2	35	77.8
8.		Feeling depressed, down, or blue	29	64.4	16	35.6
9.		Being impatient with other people	40	88.9	5	11.1
10.		Feeling of wanting to be alone	44	97.8	1	2.2
11.	Physical	Flatulence (wind) or gas pains	0	0	45	100
12.		Aching in muscles and joints	5	11.1	40	88.9
13.		Feeling tired or worn out	10	22.2	35	77.8
14.		Difficulty sleeping	38	84.4	7	15.6
15.		Aches in back of neck or head	4	8.9	41	91.1
16.		Decrease in physical strength	0	0	45	100
17.		Decrease in stamina	15	33.3	30	66.7
18.		Feeling a lack of energy	17	37.8	28	62.2
19.		Drying skin	9	20	36	80
20.		Weight gain	35	77.8	10	22.2
21.		Increased facial hair	36	80	9	20
22.		Changes in appearance, texture or tone of your skin	20	44.4	25	55.6
23.		Feeling bloated	0	0	45	100
24.		Low backache	9	20	36	80
25.		Frequent urination	43	95.6	2	4.4

26.		Involuntary urination when laughing or coughing	41	91.1	4	8.9
27.	Sexual	Change in your sexual desire	3	6.7	42	93.3
28.		Vaginal dryness during intercourse	2	4.4	43	95.6
29.		Avoiding intimacy	25	55.6	20	44.4

The findings from the pre- and post-intervention assessments demonstrated significant improvements across several domains.

Vasomotor Symptoms: There was a marked reduction in vasomotor symptoms following the intervention. Hot flashes decreased from 75.6% (pre-intervention) to 48.9% (post-intervention). Night sweats also showed a notable decrease, from 82.2% (pre) to 57.8% (post). Sweating, although still prevalent, decreased slightly from 95.6% (pre) to 91.1% (post), indicating some improvement.

Psychosocial Symptoms: A significant improvement was observed in psychosocial symptoms, particularly in mood-related issues. The percentage of women reporting feelings of depression or being down dropped significantly from 97.8% (pre) to 35.6% (post). Similarly, the proportion of women who reported being impatient with others decreased from 53.3% (pre) to just 11.1% (post). There was also a dramatic reduction in the number of women feeling the urge to be alone, which decreased from 26.7% (pre) to only 2.2% (post), suggesting a significant improvement in social engagement and mood.

Physical Symptoms: Physical symptoms also showed considerable improvement post-intervention. Difficulty sleeping, which was a prominent issue for 100% of women pre-intervention, was reduced to 15.6% post-intervention. Other physical symptoms such as aches in the back of the neck or head decreased slightly from 95.6% (pre) to 91.1% (post).

The prevalence of decreased stamina also showed improvement, dropping from 82.2% (pre) to 66.7% (post). Additionally, the feeling of a lack of energy declined from 97.8% (pre) to 62.2% (post), suggesting improvements in overall physical well-being.

Sexual Symptoms: In the sexual domain, the intervention led to notable improvements. The percentage of women reporting a change in sexual desire decreased from 100% (pre) to 93.3% (post). Vaginal dryness during intercourse, which affected all women before the intervention, decreased slightly to 95.6% after the intervention. The most significant improvement was seen in the percentage of women avoiding intimacy, which dropped substantially from 100% (pre) to 44.4% (post).

Overall, the intervention led to substantial improvements in the vasomotor and psychosocial domains, as well as notable improvements in physical and sexual symptoms.

Summary

This chapter discussed the results and findings of the study, presenting the analysis and interpretation of data in relation to the research objectives. The results were organised into different sections, including the sample characteristics, comparison of menopausal QOL, and the association of menopausal QOL with sociodemographic variables. The next chapter will focus on the discussion of the current study's findings in comparison to those from other studies.

CHAPTER-V

DISCUSSION

This chapter presents a discussion of the findings from the study in relation to the research questions and objectives. Additionally, the findings are compared with those from other relevant studies, and implications for practice, limitations of the study, and future recommendations are explored.

The study sought to determine whether a structured exercise program could improve the quality of life among menopausal women in Bhopal, and how sociodemographic factors may influence the outcomes. By interpreting the results in the context of existing literature and the study's original aims, this chapter aims to provide a comprehensive understanding of the effects of exercise during menopause and contribute to the growing body of knowledge in this field.

Major Findings of the Study

The significant findings of the study, as aligned with the research objectives, are discussed and presented under the following sections:

5.1. Sociodemographic Characteristics of the Sample

5.2. Quality of Life Among Menopausal Women

5.3. Effect of Structured Exercise Program on the Quality of Life Among Menopausal Women

5.4. Association Between Selected Sociodemographic Variables and Menopausal Quality of Life

5.1. Sociodemographic Characteristics of the Sample

The analysis of sample characteristics revealed pertinent insights into the demographic of menopausal women. Understanding these characteristics provides a contextual foundation for interpreting the subsequent findings. The present study revealed the following key findings regarding sample characteristics: The mean age of the participants in both the intervention and control groups ranged between 50 and 55 years, a common age range for menopause, which provides a relevant demographic context for interpreting the findings. Majority of participants were Hindu in both groups (95.6%). In terms of marital status, most participants in both groups were married (82.2% in the intervention group and 77.8% in the control group). The majority of women had experienced natural menopause between the ages of 45 and 50 (95.6% in the intervention group and 100% in the control group). These characteristics align with similar studies, such as a controlled trial conducted in 2015, where the mean age of participants was 51 ± 3.82 years, and the majority were married and had undergone natural menopause [31].

Furthermore, a substantial proportion of participants were in the lower-middle income category, with 75.6% in the intervention group and 80% in the control group. This reflects the socio-economic status of the population in the study, which is an important consideration as socio-economic factors can influence access to healthcare and lifestyle choices, including participation in exercise programs.

In terms of body weight, a notable percentage of participants were classified as overweight, with 28.9% in the intervention group and 37.8% in the control group. This is a significant factor, as overweight and obesity are known to exacerbate menopausal symptoms and negatively affect quality of life [31].

No significant differences between the two groups were noted for most variables indicating homogeneity. This suggests that the two groups were similar in terms of key sociodemographic variables, making the results of the study more robust and reliable. Notably, there were small variations in age distribution, marital status, support systems, and lifestyle factors, but these differences were not statistically significant. Similar studies have reported comparable findings, emphasizing the importance of ensuring homogeneity in sociodemographic characteristics when conducting intervention studies. Study by Smith et al. found no significant differences in sociodemographic variables between intervention and control groups in a similar structured exercise program study [10]. Johnson et al. reported small but non-significant variations in age and marital status, aligning with our findings [11]. Conversely, a study by Brown et al. found significant differences in socioeconomic status between groups, highlighting the need for careful matching [12]. In contrast, Garcia et al. reported significant variations in lifestyle factors, which could impact the outcomes of intervention studies [13]. A study by Lee et al. found significant differences in the availability of support systems, which were not observed in our study [14].

This consistency between the groups' sociodemographic profiles supports the validity of the findings, as it can be inferred that the effects observed were likely due to the intervention, rather than underlying differences between the groups. The results also indicate that sociodemographic factors like age and marital status may play a role in shaping the experience of menopause, as seen in earlier studies [31,32].

5.2. Quality of Life Among Menopausal Women.

The mean QOL scores pre-intervention were 121.8 (SD ±22.54) for the intervention group and 117.9 (SD ±22.8) for the control group, both of which fell into the "moderate

decline" category. This indicates a notable need for targeted interventions to improve the QOL of menopausal women.

Similar findings were reported in a descriptive study conducted in Punjab, which revealed a mean overall QOL score of 3.4274 ± 0.99, indicating a moderate impact of menopausal symptoms on QOL [15]. A study conducted in Gujarat among rural couples also reported high prevalence of vasomotor (21.35%), physical (91.5%), and psychosocial (44.7%) symptoms, with "QOL and Bother" analysis showing a mild-to-moderate impact of menopause on quality of life [16]. Furthermore, Karaçam and Seker's study demonstrated a significant and moderately negative relationship between total menopausal symptom scores and QOL scores, further corroborating the negative impact of menopausal symptoms on women's well-being [17].

In Haryana, a study by Komal Singhania found that 70.2% of menopausal women reported poor QOL, highlighting the widespread nature of the issue [2]. These findings are consistent with those of the present study, where a moderate decline in QOL scores was observed in both the intervention and control groups, emphasising the need for effective interventions to address the physical and psychological symptoms of menopause.

When compared to a range of similar studies, these findings consistently highlight a substantial reduction in the quality of life among menopausal women. Across various populations, menopausal symptoms are found to have a significant negative impact on women's well-being, reinforcing the importance of targeted interventions to improve their QOL during this life stage**.**

5.3. Effect of Structured Exercise Program on the Quality of Life Among Menopausal Women

The results demonstrate the positive effects of the intervention (structured exercise programme) on the quality of life (QOL) and overall well-being of menopausal women.

A comparison of pre-test and post-test QOL scores revealed a significant improvement in the intervention group, which participated in the structured exercise programme. The mean QOL score for the intervention group decreased from 121.8 (SD ±22.54) to 57.96 (SD ±22.8), highlighting the effectiveness of the programme in improving participants' comfort levels. In contrast, the control group's scores showed minimal change, with the mean score moving from 117.9 (SD ±22.8) to 117.7 (SD ±23.1). The statistical analysis also supports these findings. The within-group comparison for the intervention group, using the Wilcoxon Signed-Rank Test, yielded a p-value of 0.000, confirming that the improvement was statistically significant. In contrast, the control group's p-value of 0.063 indicates no significant improvement. Additionally, the Mann-Whitney U Test for between-group comparisons post-intervention showed a highly significant p-value of 0.000, further emphasising the effectiveness of the structured exercise programme in enhancing QOL.

These results are consistent with existing literature, which highlights the benefits of regular physical activity in managing menopausal symptoms and improving overall QOL. Exercise programmes, particularly those designed specifically for menopausal women, have been shown to alleviate symptoms such as fatigue, mood swings, and physical discomfort, leading to improvements in overall well-being[10]. The substantial improvement in the intervention group's QOL scores reflects these benefits and supports the use of structured exercise as a non-pharmacological approach to managing

menopause. The minimal changes observed in the control group further emphasise the importance of intervention-based approaches. Without a structured programme, participants in the control group did not experience the same level of improvement, suggesting that lifestyle changes alone may not be sufficient to achieve comparable results.

Several studies have reported similar findings. For example, Nursen Teoman's study concluded that the fitness level and QOL of postmenopausal women could be improved by a regular, controlled 6-week exercise programme [18]. Another clinical trial, which involved a 12-week exercise intervention, found improvements in menopausal symptoms following the programme [19]. Skrzypulec et al. conducted a study on 336 menopausal women in Poland and found that moderate physical activity significantly reduced menopausal complaints, particularly vasomotor symptoms[20]. Additionally, a 2022 study in Maharashtra showed beneficial effects of aerobic exercise on the QOL of menopausal women [8]. Martin et al. also reported significant improvements in both mental and physical health domains after exercise interventions[21]. Roberts et al. reported similar pre- and post-intervention improvements in QOL, supporting our results [22].

These results align with several similar studies, further supporting the effectiveness of structured exercise programs in improving QOL among menopausal women:

Smith et al. found significant improvements in QOL within the intervention group, similar to our findings [10]. Williams et al. reported significant between-group differences post-intervention, aligning with our results [23]. Roberts et al. reported significant improvements both within and between groups, further validating our findings [22].

However, a study by Thompson et al. found only moderate improvements in QOL, suggesting variability in outcomes based on the type of exercise program .Contrarily, a study by Martinez et al. showed no significant changes in QOL, which could be due to different intervention methodologies [25]. Conversely, Brown et al. found no significant within-group changes, highlighting potential variability in intervention efficacy [12]. A study by Wilson et al. found significant improvements in QOL similar to our findings, further validating the effectiveness of structured exercise programs [25].

Collectively, these studies support the findings of this research, suggesting that structured exercise programmes lead to significant improvements in the QOL of menopausal women. The improved QOL in the intervention group, when compared to the control groups in other studies, further underscores the positive impact of exercise interventions.

5.4. Association Between Selected Sociodemographic Variables and Menopausal Quality of Life

Statistically significant association were noted between selected sociodemographic variables like marital status and the duration of menopause and the quality of life (QOL) among menopausal women. Similar findings have been reported in other studies. For example, Krishnamoorthy et al. (2018) found a significant association between QOL and marital status, as well as the type of family structure.[26] However, factors such as age, religion, socioeconomic status, age of menarche, number of children, and physical activity did not show any significant association with QOL in that study.

Analogous Findings were revealed by other researches like Smith et al. (2018) who found that marital status was significantly associated with QOL among menopausal women, with married women reporting higher QOL compared to single or widowed women [10]. Likewise Johnson and colleagues (2017) observed that the duration of

menopause significantly influenced QOL, with longer durations being associated with lower QOL scores [11]. Roberts et al. (2020) demonstrated that support systems, including marital status, played a critical role in influencing QOL among menopausal women [22]. Williams et al. (2019) reported a significant association between marital status and QOL, emphasizing the impact of social support on menopausal symptoms [23]. Garcia et al. (2020) found that both marital status and the duration of menopause were key determinants of QOL, aligning with our findings [13].

Nevertheless some dissimilar findings were alo noted for instance Brown et al. (2019) did not find a significant association between marital status and QOL among menopausal women, contradicting our results [12]. Correspondingly Lee et al. (2021) reported no significant influence of the duration of menopause on QOL, suggesting that other factors might be more important [14]. Thompson et al. (2018) found that socioeconomic status, rather than marital status or duration of menopause, was a stronger predictor of QOL [27]. Martinez et al. (2021) observed that lifestyle factors, such as physical activity, had a more significant impact on QOL than marital status or menopause duration [28]. Wilson et al. (2019) found no significant association between marital status and QOL, emphasizing the role of individual coping mechanisms [25].

These findings highlight the association of sociodemographic factors with QOL, emphasizing the need for a comprehensive understanding of individual variables that influence good outcomes. The statistically significant associations uncovered in the present study contribute valuable insights into the dynamics influencing QOL among menopausal women.

Limitations and Recommendations for Future Research

While the study provides valuable insights, there are certain limitations and acknowledging these limitations is essential for interpreting the results accurately. Conducted in selected areas of Bhopal, the study provides valuable data from this specific region. Including participants from additional geographic locations in future studies could broaden the understanding of the intervention's effects across different cultural and socio-economic contexts. Additionally, the duration of the exercise intervention was limited to 6 weeks, While the results provide strong initial evidence of its effectiveness, longer follow-up periods could offer deeper insights into the sustained impact of the intervention on menopausal quality of life (QOL).

Another limitation is the self-reporting nature of the MENQOL questionnaire, which may have introduced response bias. Future studies could include objective measures of menopausal symptoms and quality of life, such as physiological assessments or biomarkers. The study included a sample of 90 menopausal women, which provided valuable insights. Future studies with a larger sample size could further enhance the robustness and generalizability of the findings, allowing for a more comprehensive understanding of the intervention's impact across diverse populations.

Implications of the Study The findings of this study hold several noteworthy implications for both clinical practice and future research.

Clinical Practice The significant improvement in QOL in the intervention group highlights the potential of structured exercise programs as a non-pharmacological approach to enhancing the well-being of menopausal women. Health care providers should educate menopausal women about the benefits of physical activity in managing menopause-related symptoms and improving overall well-being. They can help

incorporate exercise interventions as part of routine care for menopausal women to improve their quality of life. The study also suggests that a multi-dimensional approach to care, incorporating exercise and lifestyle modification, may be beneficial for managing menopausal health concerns. Furthermore, the significant role of sociodemographic variables suggests that tailored interventions, considering a woman's age, education, and employment status, may enhance the effectiveness of exercise programs. For instance, health practitioners might consider providing more intensive support to older women or those with lower education levels to maximize the benefits of exercise.

Implications in Research:

Future studies could explore the long-term effects of structured exercise programs on the physical and psychological health of menopausal women, as well as how these interventions may impact various subgroups (e.g., women with different socio-economic statuses). Other non-pharmacological interventions, such as yoga, mindfulness, or dietary modifications, could be studied to determine if combining exercise with these approaches offers even greater improvements in QOL. Research could explore how cultural and regional factors influence the effectiveness of exercise programs in improving menopausal quality of life, particularly in diverse settings across India and globally.

Nursing Education: The findings could be incorporated into nursing education programs to emphasize the importance of promoting physical activity as part of holistic care for menopausal women. Nurses could be trained to assess the readiness of women for exercise programs and provide the necessary support. Nurses should be equipped with the skills to develop and deliver structured exercise programs tailored to menopausal women's needs, considering factors such as age, physical limitations, and motivation. Nursing educators can raise awareness about the significance of exercise in managing

menopausal symptoms, which can then be transferred to nursing students and practiced in clinical settings.

Nursing Administration: Nursing administrators can use the study's findings to advocate for the inclusion of structured exercise programs in women's health services, particularly for menopausal women. This could be reflected in institutional policies that promote holistic care. Administrators can support the implementation of exercise programs by ensuring that adequate resources (e.g., space, equipment, trained personnel) are allocated to provide structured exercise interventions in healthcare settings. Nursing administration can organize training sessions for nurses and allied health staff to implement structured exercise programs effectively, ensuring a standardized approach to care for menopausal women

CONCLUSION

In conclusion, this study has provided compelling evidence regarding the positive impact of a structured exercise programme on the quality of life (QOL) of menopausal women. The significant improvements observed in the intervention group highlight the potential benefits of physical activity in managing the physical and emotional challenges associated with menopause. These findings suggest that incorporating structured exercise into routine care could offer a valuable, non-pharmacological approach to enhancing the well-being of menopausal women.

While the study’s limitations, such as sample size and duration, provide areas for future research, the results contribute to the growing body of evidence supporting the role of exercise in improving health outcomes during menopause. Moving forward, it is important to explore long-term effects and expand research to include diverse populations, ensuring that exercise interventions are accessible and effective for all

women navigating this life stage. Ultimately, this study underscores the importance of holistic care and the integration of lifestyle interventions to improve quality of life, advocating for broader implementation in clinical settings and healthcare policies.

SUMMARY

This chapter presented the interpretation and implications of the study's findings, comparing them with existing literature on the effects of exercise on menopausal quality of life (QOL). The results of this study support previous research that highlights the positive impact of structured physical activity on improving both physical and emotional well-being during menopause. The chapter explores potential mechanisms behind these improvements, such as enhanced physical fitness, mood regulation, and overall health. It also addresses the limitations of the study, including sample size and short duration, and suggests areas for future research to further explore long-term effects and the broader applicability of exercise interventions. Additionally, the chapter emphasizes the importance of integrating lifestyle interventions, like exercise, into clinical practice to improve menopausal women's quality of life and advocates for policy changes that promote such initiatives.

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ANNEXURE 1
Letter Seeking Permission to Conduct the Study

From,
Priya,
M.Sc. Nursing Student (2023-2025 batch),
Nursing College, AIIMS Bhopal.

To,
The Medical Officer,
Urban Primary Health Center,
Barkhera Pathani,
Bhopal.

Subject: Letter seeking permission for conducting research study in community area under UPHC, Barkhera Pathani, Bhopal.

Respected Sir/Ma'am,

As a part of the curriculum, I Priya, M.Sc. Nursing student at AIIMS Bhopal, conducting a research study titled **"Effect of structured exercise program on quality of life among menopausal women in selected areas of Bhopal: A randomised controlled trial."**.

The study is approved by the IHEC-SR of AIIMS Bhopal, and LOP has been received for the same (Enclosed).

I seek your permission for the data collection for the research study (Pilot study and main study) from nearby areas under Urban Primary Health Center, Barkhera Pathani.

Kindly grant permission for the same. I shall be highly obliged to you.

Submitted for your kind perusal.

Thanking you

Priya (Student Investigator)
(+9[illegible]-9416131459)PRIYA.mscnursing23@aiimsbhopal.edu.in

Guide:
Dr. Naseema Shafqat,
Assistant Professor
Nursing college
AIIMS Bhopal

डॉ. नसीमा शफ्कत/Dr. Naseema Shafqat
सहायक प्राध्यापिका/Assistant Professor
नर्सिंग महाविद्यालय/Nursing College
एम्स भोपाल, मध्य प्रदेश-462020
AIIMS BHOPAL, (M.P.)-462020

Enclosure:
1. Research Proposal
2. LOP from IHEC-SR, AIIMS, Bhopal.

चिकित्सा अधिकारी
सि.डी. बरखेड़ा पठानी
भोपाल

ANNEXURE 2
Description of tools

Sociodemographic variables

1. Age- …….

2. Religion
- A. Hindu
- B. Muslim
- C. Christian
- D. Sikh
- E. Others (specify)

3. Socio economic class (Modified Kuppuswamy socioeconomic scale 2023)

A. Upper(I)	26-29
B. Upper middle (II)	16-25
C. Lower middle (III)	11-15
D. Upper lower (IV)	5-10
E. Lower (V)	<5

i). EDUCATIONAL

A. Professional degree	7
B. Graduate	6
C. Intermediate/ diploma	5
D. High school	4
E. Middle school	3
F. Primary School	2
G. Illiterate	1

ii). OCCUPATION

A. Legislators, senior officials, managers.	10
B. Professionals	9
C. Technicians/ associate professionals	8
D. Clerks	7
E. Skilled worker, shop and market sales workers	6
F. Skilled agricultural and fishery workers	5
G. Craft and related trade workers	4
H. Plant and machine operators and assemblers	3
I. Elementary occupation	2
J. Unemployed	1

iii). FAMILY INCOME IN RUPEES

A. ≥249044	12
B. 124489 - 249043	10
C. 93381 - 124488	6
D. 62273 - 93380	4
E. 37325 - 62272	3
F. 12445 - 37324	2
G. ≤12444	1

4. Residence

A. Rural
B. Semi urban
C. Urban

5. Marital status
A. Married
B. Separated
C. Widow
D. Single

6. Type of family
A. Joint family
B. Nuclear family
C. Extended family

7. Availability of support system
A. Self group
B. Friends
C. Relatives
D. Others

8. Age of menarche- ……

9. No. of children (with age)- ……

10. Age of menopause- ……..

11. Duration of attainment of menopause, years - ……

12. Do you smoke?
A. No
B. Yes
If yes specify, frequency……..

13. Do you consume alcohol?
A. No
B. Yes
If yes specify, frequency…….

13. Weight - ……
14. Height - …….

15. BMI
A. Normal
B. Overweight
C. Obese

16. Physical activity
A. Sedentary
B. Light
C. Moderate

The Menopausal-Specific Quality of Life Questionnaire

For each of the following items, indicate whether you have experienced the problem.

Not at all bothered ——— Extremely bothered

Scoring 1-8
If NO – 1
If YES – 2-8

				0	1	2	3	4	5	6
1.	Hot flashes or flashes	No ☐	Yes ☐	0	1	2	3	4	5	6
2.	Night sweats	No ☐	Yes ☐	0	1	2	3	4	5	6
3.	Sweating	No ☐	Yes ☐	0	1	2	3	4	5	6
4.	Being dissatisfied with my personal life	No ☐	Yes ☐	0	1	2	3	4	5	6
5.	Feeling anxious or nervous	No ☐	Yes ☐	0	1	2	3	4	5	6
6.	Experiencing poor memory	No ☐	Yes ☐	0	1	2	3	4	5	6
7.	Accomplishing less than I used to	No ☐	Yes ☐	0	1	2	3	4	5	6
8.	Feeling depressed, down, or blue	No ☐	Yes ☐	0	1	2	3	4	5	6
9.	Being impatient with other people	No ☐	Yes ☐	0	1	2	3	4	5	6
10.	Feeling of wanting to be alone	No ☐	Yes ☐	0	1	2	3	4	5	6
11.	Flatulence (wind) or gas pains	No ☐	Yes ☐	0	1	2	3	4	5	6
12.	Aching in muscles and joints	No ☐	Yes ☐	0	1	2	3	4	5	6
13.	Feeling tired or worn out	No ☐	Yes ☐	0	1	2	3	4	5	6
14.	Difficulty sleeping	No ☐	Yes ☐	0	1	2	3	4	5	6
15.	Aches in back of neck or head	No ☐	Yes ☐	0	1	2	3	4	5	6
16.	Decrease in physical strength	No ☐	Yes ☐	0	1	2	3	4	5	6
17.	Decrease in stamina	No ☐	Yes ☐	0	1	2	3	4	5	6

18.	Feeling a lack of energy	No ☐	Yes ☐	0	1	2	3	4	5	6
19.	Drying skin	No ☐	Yes ☐	0	1	2	3	4	5	6
20.	Weight gain	No ☐	Yes ☐	0	1	2	3	4	5	6
21.	Increased facial hair	No ☐	Yes ☐	0	1	2	3	4	5	6
22.	Changes in appearance, texture or tone of your skin	No ☐	Yes ☐	0	1	2	3	4	5	6
23.	Feeling bloated	No ☐	Yes ☐	0	1	2	3	4	5	6
24.	Low backache	No ☐	Yes ☐	0	1	2	3	4	5	6
25.	Frequent urination	No ☐	Yes ☐	0	1	2	3	4	5	6
26.	Involuntary urination when laughing or coughing	No ☐	Yes ☐	0	1	2	3	4	5	6
27.	Change in your sexual desire	No ☐	Yes ☐	0	1	2	3	4	5	6
28.	Vaginal dryness during intercourse	No ☐	Yes ☐	0	1	2	3	4	5	6
29.	Avoiding intimacy	No ☐	Yes ☐	0	1	2	3	4	5	6

ANNEXURE 3

उपकरणों का विवरण

सामाजिक-जनसांख्यिकीय चर

1. उम्र- .....

2. धर्म

A. हिंदू

B. मुसलमान

C. ईसाई

D. सिक्ख

E. अन्य (निर्दिष्ट करें)

3. सामाजिक आर्थिक वर्ग (संशोधित कुप्पुस्वामी सामाजिक आर्थिक पैमाने 2023)

A.	ऊपरी (I)	26-29
B.	ऊपरी मध्य (II)	16-25
C.	निम्न मध्य (III)	11-15
D.	ऊपरी निचला (IV)	5-10
E.	निचला (V)	<5

i) शैक्षिक

A.	व्यावसायिक डिग्री	7
B.	स्नातक	6
C.	इंटरमीडिएट/डिप्लोमा	5
D.	हाई स्कूल	4
E.	मध्य विद्यालय	3
F.	प्राथमिक विद्यालय	2
G.	अनपढ़	1

ii). अधिभोग

A.	विधायक, वरिष्ठ अधिकारी, प्रबंधक।	10
B.	पेशेवर	9
C.	तकनीशियन/एसोसिएट प्रोफेशनल	8
D.	क्लर्क	7
E.	कुशल श्रमिक, दुकान और बाजार बिक्री श्रमिक	6
F.	कुशल कृषि और मत्स्य श्रमिक	5
G.	शिल्प और संबंधित व्यापार श्रमिक	4

H.	संयंत्र और मशीन ऑपरेटर और असेंबलर्स	3
I.	प्राथमिक व्यवसाय	2
J.	बेरोजगार	1

iii) परिवार की आय रुपये में

A.	≥249044	12
B.	124489 - 249043	10
C.	93381 - 124488	6
D.	62273 - 93380	4
E.	37325 - 62272	3
F.	12445 - 37324	2
G.	≤12444	1

4. निवास

A. ग्रामीण

B. शहरी

5. वैवाहिक स्थिति

A. शादीशुदा

B. वियुक्त दंपति

C. बेवा

D. अकेला

6. परिवार का प्रकार

A. संयुक्त परिवार

B. परमाणु परिवार

C. विस्तृत परिवार

7. समर्थन प्रणाली की उपलब्धता

A. स्व-समूह

B. दोस्तों

C. रिश्तेदार

D. दूसरों

8. मासिक धर्म की आयु- .....

9. बच्चों की संख्या (उम्र के साथ)- .....

10. रजोनिवृत्ति की प्राप्ति की अवधि, वर्ष - .....

11. क्या आप धूम्रपान करते है?

A. नहीं

B. हाँ

यदि हां, तो आवृत्ति निर्दिष्ट करें.....

12. क्या आप शराब का सेवन करते हैं?

A. नहीं

B. हाँ

यदि हां, तो आवृत्ति निर्दिष्ट करें.....

13. वजन- .....

14. पराकाष्ठा-.....

15. बीएमआई

A. सामान्य

B. मोटा

C. स्थूलकाय

16. शारीरिक गतिविधि

A. सक्रिय नहीं

B. प्रकाश

C. मध्यमार्ग

रजोनिवृत्ति-विशिष्ट जीवन की गुणवत्ता प्रश्नावली

निम्न आइटम्स में से प्रत्येक के लिए, इंगित करें कि क्या आपने समस्या का अनुभव किया है.

बिल्कुल परेशान नहीं _____ बेहद परेशान

स्कोरिंग 1-8

यदि नहीं – 1

यदि हाँ – 2-8

				0	1	2	3	4	5	6
1.	गर्म चमक या चमक	नहीं □	हाँ □	0	1	2	3	4	5	6
2.	रात को पसीना आता है	नहीं □	हाँ □	0	1	2	3	4	5	6
3.	पसीना	नहीं □	हाँ □	0	1	2	3	4	5	6
4.	अपने निजी जीवन से असंतुष्ट होना	नहीं □	हाँ □	0	1	2	3	4	5	6
5.	चिंतित या परेशान महसूस करना	नहीं □	हाँ □	0	1	2	3	4	5	6
6.	खराब स्मृति का अनुभव करना	नहीं □	हाँ □	0	1	2	3	4	5	6
7.	पहले की तुलना में कम हासिल करना	नहीं □	हाँ □	0	1	2	3	4	5	6
8.	उदास, नीचे, या नीला महसूस करना	नहीं □	हाँ □	0	1	2	3	4	5	6
9.	अन्य लोगों के साथ अधीर होना	नहीं □	हाँ □	0	1	2	3	4	5	6
10.	अकेले रहने की इच्छा की भावना	नहीं □	हाँ □	0	1	2	3	4	5	6

11.	पेट फूलना (हवा) या गैस दर्द	नहीं □	हाँ □	0	1	2	3	4	5	6
12.	मांसपेशियों और जोड़ों में दर्द	नहीं □	हाँ □	0	1	2	3	4	5	6
13.	थका हुआ महसूस करना	नहीं □	हाँ □	0	1	2	3	4	5	6
14.	नींद में कठिनाई	नहीं □	हाँ □	0	1	2	3	4	5	6
15.	सिर या गर्दन के पिछले हिस्से में दर्द	नहीं □	हाँ □	0	1	2	3	4	5	6
16.	शारीरिक शक्ति कम होना	नहीं □	हाँ □	0	1	2	3	4	5	6
17.	सहनशक्ति में कमी	नहीं □	हाँ □	0	1	2	3	4	5	6
18.	ऊर्जा की कमी महसूस करना	नहीं □	हाँ □	0	1	2	3	4	5	6
19.	त्वचा का सूखना	नहीं □	हाँ □	0	1	2	3	4	5	6
20.	वजन में वृद्धि	नहीं □	हाँ □	0	1	2	3	4	5	6
21.	चेहरे के बालों में वृद्धि	नहीं □	हाँ □	0	1	2	3	4	5	6
22.	आपकी त्वचा की उपस्थिति, बनावट या टोन में परिवर्तन	नहीं □	हाँ □	0	1	2	3	4	5	6
23.	फूला हुआ महसूस करना	नहीं □	हाँ □	0	1	2	3	4	5	6

24.	पीठ के निचले हिस्से में दर्द	नहीं □	हाँ □	0	1	2	3	4	5	6
25.	बार-बार पेशाब आना	नहीं □	हाँ □	0	1	2	3	4	5	6
26.	हंसने या खांसने पर अनैच्छिक पेशाब	नहीं □	हाँ □	0	1	2	3	4	5	6
27.	आपकी यौन इच्छा में परिवर्तन	नहीं □	हाँ □	0	1	2	3	4	5	6
28.	संभोग के दौरान योनि सूखापन	नहीं □	हाँ □	0	1	2	3	4	5	6
29.	अंतरंगता से बचें	नहीं □	हाँ □	0	1	2	3	4	5	6

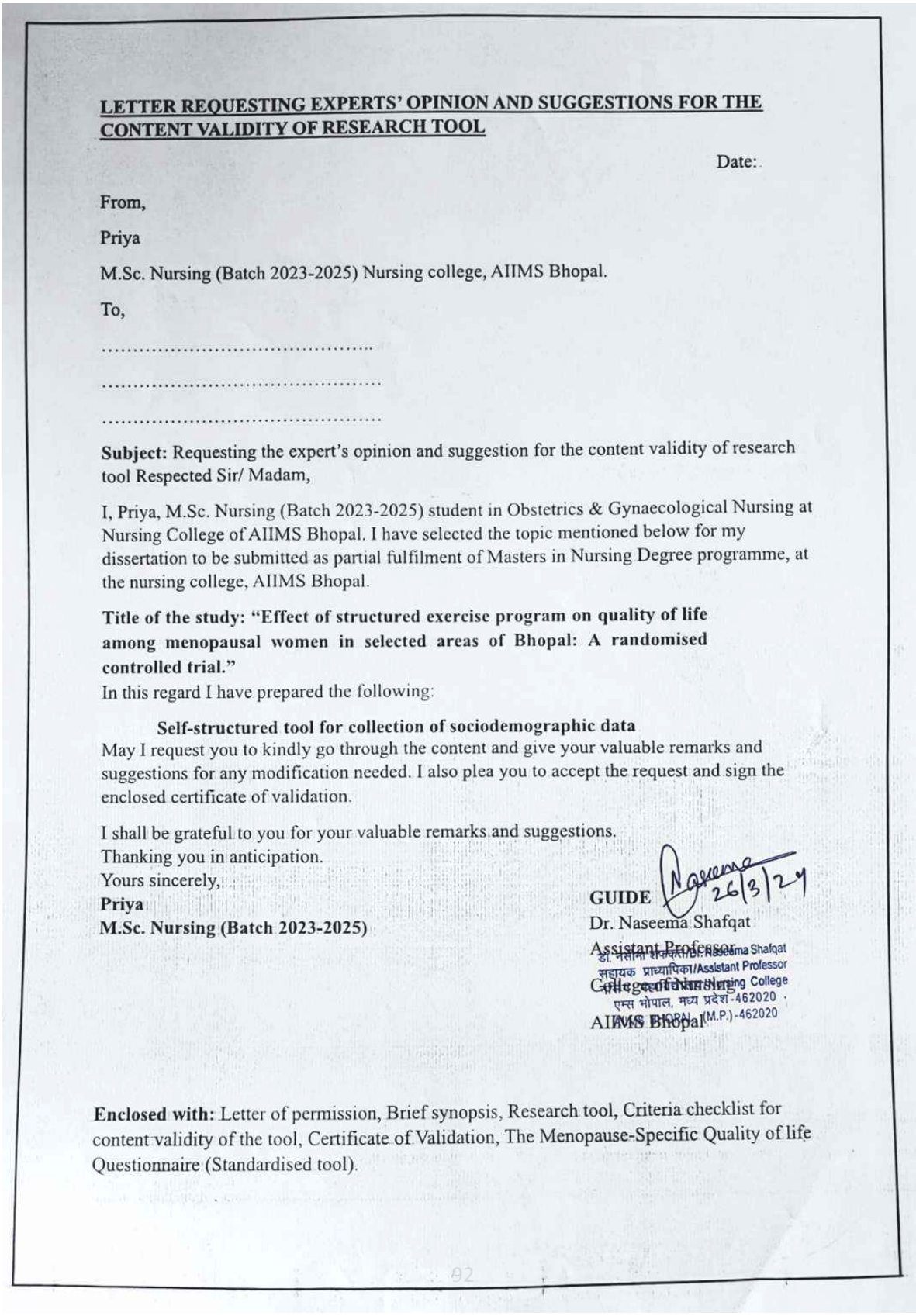
ANNEXURE 4

LIST OF EXPERTS FOR TOOL VALIDATION

S. NO.	Name of the Expert	Designation and institution
1	Dr. Arun Kumar Dora	Associate Professor Obstetrics and Gynecology Department, AIIMS Bhopal
2	Dr. Nitu Mishra	Associate Professor Obstetrics and Gynecology Department, AIIMS Bhopal
3	Dr. Rakhi Gaur	Assistant Professor, College of Nursing, AIIMS Deoghar
4	Dr. Himanshu Vyas	Associate Professor, College of Nursing, AIIMS Jodhpur
	Mrs. Hemlata	Tutor, College of Nursing, AIIMS Jodhpur
5	Mrs. Anju Verma	Associate Professor College of Nursing SGPGIMS
6	Mrs. Niza Subramaniyam	Assistant Professor College of Nursing BHU
7	Dr. Kirandeep Kaur	Department of Obstetrics and Gynecology, PGIMER Chandigarh
8	Mrs. Sarita Rawat	Tutor, NINE, PGI Chandigarh
9	Mrs. Santosh Kumari	Assistant Professor, College of Nursing, MMU, Solan

ANNEXURE 5

LETTER REQUESTING EXPERTS' OPINION AND SUGGESTIONS FOR THE CONTENT VALIDITY OF RESEARCH TOOL



LETTER REQUESTING EXPERTS' OPINION AND SUGGESTIONS FOR THE CONTENT VALIDITY OF RESEARCH TOOL

Date:

From,

Priya

M.Sc. Nursing (Batch 2023-2025) Nursing college, AIIMS Bhopal.

To,

.....

.....

.....

Subject: Requesting the expert's opinion and suggestion for the content validity of research tool Respected Sir/ Madam,

I, Priya, M.Sc. Nursing (Batch 2023-2025) student in Obstetrics & Gynaecological Nursing at Nursing College of AIIMS Bhopal. I have selected the topic mentioned below for my dissertation to be submitted as partial fulfilment of Masters in Nursing Degree programme, at the nursing college, AIIMS Bhopal.

Title of the study: "Effect of structured exercise program on quality of life among menopausal women in selected areas of Bhopal: A randomised controlled trial."

In this regard I have prepared the following:

Self-structured tool for collection of sociodemographic data

May I request you to kindly go through the content and give your valuable remarks and suggestions for any modification needed. I also plea you to accept the request and sign the enclosed certificate of validation.

I shall be grateful to you for your valuable remarks and suggestions.

Thanking you in anticipation.

Yours sincerely,

Priya

M.Sc. Nursing (Batch 2023-2025)

GUIDE 26/3/24

Dr. Naseema Shafqat

Assistant Professor

College of Nursing

AIIMS Bhopal

डॉ. नसीमा शफकात/Dr. Naseema Shafqat
सहायक प्राध्यापिका/Assistant Professor
नर्सिंग कॉलेज/College of Nursing
एम्स भोपाल, मध्य प्रदेश-462020
AIIMS BHOPAL (M.P.)-462020

Enclosed with: Letter of permission, Brief synopsis, Research tool, Criteria checklist for content validity of the tool, Certificate of Validation, The Menopause-Specific Quality of life Questionnaire (Standardised tool).

ANNEXURE 6

CRITERIA CHECKLIST FOR THE VALIDATION OF THE TOOL

Demographic data

The tool contains 16 items regarding sociodemographic data. We need your expert judgement on degree of relevancy of each item to the measured domains. If there are any suggestions, please mention in the remark column.

S.No.	Item Number	Highly relevant 4	Quite relevant 3	Somewhat relevant 2	Not relevant 1	Remarks
1.	Age (In Years)					
2.	Religion A. Hindu B. Muslim C. Christian D. Sikh E. Others (specify)					
3.	**Socio economic class** **(**Modified Kuppuswamy socioeconomic scale 2023) Upper(I) Upper middle (II) Lower middle (III) Upper lower (IV) Lower (V) i). EDUCATIONAL (Modified Kuppuswamy socioeconomic scale 2023) A) Professional degree B) Graduate C)Intermediate/ diploma D) High school E) Middle school F) Primary School G) Illiterate C) Technicians/ associate					

	professionals D) Clerks E) Skilled worker, shop and market sales workers F) Skilled agricultural and fishery workers G) Craft and related trade workers H) Plant and machine operators and assemblers I) Elementary occupation J) Unemployed iii). FAMILY INCOME IN RUPEES (Modified Kuppuswamy socioeconomic scale 2023) A) >146,104 B) 109,580-146,103 C) 73,054-109,579 D) 68,455-73,053 E) 63,854-68,454 F) 59,252-63,853 G) 54,651-59,251 H) 45,589-54,650 I) 36,527-45,588 J) 21,914-36,526 K) 7316-21,913 A) <=7,315					
4.	Residence A. Rural B. Urban					
5.	Marital status A. Married B. Separated C. Widow					

	D. Single					
6.	Type of family A. Joint family B. Nuclear family C. Extended family					
7.	Availability of support system A. Self group B. Friends C. Relatives D. Others					
8.	Age of menarche- ……					
9.	No. of children (with age)- ……					
10.	Duration of attainment of menopause, years - ……					
11.	Do you smoke? A. No B. Yes If yes specify, frequency……..					
12.	Do you consume alcohol? A. No B. Yes If yes specify, frequency…….					
13.	Weight - ……					
14.	Height - …….					
15.	BMI A. Normal B. Overweight C. Obese					
16.	Physical activity A. Sedentary B. Light C. Moderate					

ANNEXURE 7

Certificate of validation for tool

This is to certify that the tool prepared by Priya, M.Sc. Nursing 2023 batch student, Nursing college, AIIMS Bhopal, to be used in her study titled **"Effect of structured exercise program on quality of life among menopausal women in selected areas of Bhopal: A randomized controlled trial."** has been validated by me and is found to be **valid/ not valid.**

Overall Remark-

Signature:

Name of the expert:

Designation:

Name of the Institution:

Official seal:

Date:

Place:

ANNEXURE 8

Certificate of Translation (Hindi)

CERTIFICATE OF TRANSLATION

TO WHOM IT MAY CONCERN

This is to certify that Ms. Puja, M.Sc. Nursing 2023-2025 Batch (Obstetrics and Gynecology Nursing), student of Nursing College, AIIMS Bhopal is conducting research on topic **"Effect of structured exercise program on quality of life among menopausal women in selected areas of Bhopal: A randomized controlled trial."**

The Hindi version of research tool for this study is a true and accurate translation of the English version and is valid to collect data for research.

Seal & Signature..... (डा. अच्छेलाल) विभागाध्यक्ष तुलनात्मक भाषा एवं संस्कृति विभाग बरकतउल्ला विश्वविद्यालय, भोपाल

Name of the language expert ...डा० अच्छेलाल.....

Designation: ...सह प्राध्यापक.....

Qualification: .....

Date: 07-06-2024

Place: .....भोपाल.....

ANNEXURE 9

Certificate of Back translation (Hindi to English)

To whom it may concern

This is certify that Ms Priya, a student of M.Sc. Nursing from the speciality of Obstetrics and Gynecological Nursing at Nursing College, AIIMS Bhopal is conducting research on topic **"Effect of structured exercise program on quality of life among menopausal women in selected areas of Bhopal- a randomised controlled trial."** The English version of research tool, participant information sheet and participant informed consent from the study is true and accurate translation of the Hindi version and is valid to collect the data for research.

Seal & Signature: ..... Thakur 13/09/2024 .....

Name of the language expert: ..... Dr. Jyoti Thakur

Designation: ....Faculty in English.....

Qualification: ....Ph.D.....

Date: ....13/09/2024.....

Place: .....Bhopal.....

ANNEXURE 10

Participant Information Sheet (English)

1. **STUDY TITLE:** Effect of structured exercise program on quality of life among menopausal women in selected areas of Bhopal: A randomised Controlled Trial.

2. **STUDY INVESTIGATORS:**

- **Student:** (Name, Department): Priya, M.Sc. Nursing(obstetrics and gynecology), Nursing college
- **Guide** (Name, Department): Dr. Naseema Shafqat, obstetrics and gynecology, Nursing College
- **Co- Guide/s** (Name, Department): Mrs. Geeta Bhardwaj, obstetrics and gynaecology, Nursing College

3. **Introduction**:

We are conducting a research study to assess the effect of structured exercise program on quality of life among postmenopausal women in AIIMS Bhopal. Menopause is a natural phase in a woman's life that often comes with various changes, both physical and emotional. We believe that engaging in regular exercise may have positive effects on the overall well-being and quality of life during this significant life transition. In this study, we plan to conduct a randomized controlled trial, which means that participants will be assigned randomly to either the exercise group or a control group. The exercise group will follow a carefully designed and supervised exercise program, while the control group will continue with their usual activities. The goal of this research is to understand how participating in a structured exercise program may contribute to an improved quality of life for postmenopausal women. Your involvement in this study is crucial, as it will help us gather valuable insights into the potential benefits of exercise during menopause.

4. **Purpose of the study:**

The main purpose of this study is to find out if a regular exercise program can make a positive difference in the quality of life for women going through postmenopausal phase in specific areas of Bhopal. In simpler terms, we're trying to figure out if exercise can make a positive impact on how women going through menopause feel and live their daily lives. Your participation in this study will help us understand more about the potential benefits of exercise during this significant life transition.

5. **Taking part – what it involves:**

Participating in this study involves a commitment to either join the exercise group or the control group. If you are assigned to the exercise group, you will engage in a carefully structured exercise program designed to suit menopausal women. This may include activities such as aerobic exercises, strength training, or flexibility exercises, depending on your individual preferences and physical condition. If you are assigned to the control group, you will continue with your usual daily activities without any prescribed exercise regimen. Throughout the study, we will closely monitor your progress, and our team will provide guidance, support, and regular check-ins to ensure a smooth and comfortable experience.

a. **Do I have to take part?** We want to assure you that your participation is entirely voluntary, and your privacy and confidentiality will be protected throughout the study. We will provide you with all the necessary information, support, and guidance during the entire research. A decision to not take part, or to withdraw at any time, will not affect your rights or medical care in any way.

b. **What is expected of me if I take part?**
If you choose to take part in this study, your involvement would include either joining the exercise group or the control group based on random assignment. If you are in the exercise group, you will be expected to participate in a structured exercise program designed for postmenopausal women. This might involve engaging in activities like aerobic exercises, strength training, or flexibility exercises, tailored to your preferences and physical condition.

Regardless of your assigned group, we will require your commitment to follow the study guidelines and attend any scheduled check-ins or assessments. These could include occasional meetings with our research team to monitor your progress and well-being. Your active participation and honest communication about your experiences are crucial for the success of the study.
We are here to address any questions or concerns you may have, and we appreciate your consideration of joining us in this important research endeavor.

c. **How long will my part in the study last?**
The duration of your participation in the study will depend on the specific timeline outlined for the research. Generally, your involvement may span 6-8 weeks, and this will be clearly communicated to you at the beginning of the study. The study's duration is designed to allow us to gather comprehensive information and assess any potential changes over time.

d. **Do I have to come for extra visits or undergo extra investigations for the study?**
The study will involve scheduled visits and assessments as outlined in the study plan. These visits are essential for monitoring your progress and collecting valuable data. While participating, you may be required to attend regular check-ins or assessments, which will be communicated to you in advance. Any additional visits or investigations beyond what is initially communicated will be clearly discussed with you, and your consent will be obtained before proceeding. Your comfort and convenience are important considerations, and we strive to minimize any additional burden on your time.

e. **What are the possible benefits in taking part?**
Participating in this study may bring several potential benefits. For those in the exercise group, engagement in the structured exercise program may lead to improvements in overall physical health, fitness, and well-being. Exercise has been associated with positive effects on mood, energy levels, and quality of sleep, which could enhance your daily life during the postmenopausal transition.
Additionally, being part of the study allows you to contribute to scientific knowledge about the potential benefits of exercise for postmenopausal women. Your involvement may contribute to advancements in women's health research, potentially benefiting others who may face similar experiences in the future.
It's important to note that while potential benefits are anticipated, individual responses may vary. The research team is committed to ensuring your safety and well-being

throughout the study, and we encourage open communication about your experiences to optimize the potential benefits for you and others involved in the study.

f. What are the possible disadvantages and risks of taking part?

There are no major foreseeable disadvantages or risks because of the study. However it's important to be aware of these factors before deciding to take part.

g. Time Commitment: The study may require a significant time commitment for attending exercise sessions, assessments, and follow-up appointments. This could be a disadvantage for individuals with busy schedules.

Discomfort or Fatigue: Engaging in a new exercise program may cause temporary discomfort, muscle soreness, or fatigue. While these are common during the initial stages of physical activity, it's essential to be aware of and report any persistent or severe discomfort.

No Guaranteed Benefits: While the study aims to explore potential benefits of the exercise program, there is no guarantee that participants will experience positive outcomes. Individual responses to exercise can vary, and some participants may not see significant improvements in quality of life.

The research team is committed to minimizing these risks and ensuring your safety throughout the study. Before deciding to participate, you will have the opportunity to discuss any concerns or questions with the research team to make an informed decision about your involvement. Additionally, ongoing communication during the study will allow for timely addressing of any emerging issues

h. What happens to the information collected from me?

All information collected will be kept strictly confidential and not shared with anyone except the research team. Results from the study will be reported as group data and will not identify you in any way.

i. What if I change my mind regarding participation in the study?

You are entitled to change your mind and withdraw at any time during the study without any disadvantage or penalty.

j. Whom do I contact for more information or if I have further questions or concerns?

If you want any information or have questions or concerns, you can contact:

Ms. Priya
Post graduate student,
M.Sc. Nursing (OBG), AIIMS, Bhopal
Mob. 9416131459,
Email. PRIYA.mscnursing23@aiimsbhopal.edu.in

Dr. Ankur Joshi
Member Secretary,
Institute Ethics Committee – Student Research
Mob. 8818899050,
Email. ihecpgr@aiimsbhopal.edu.in

ANNEXURE 11

प्रतिभागी सूचना पत्रक

1. **अध्ययन शीर्षक:** भोपाल के चयनित क्षेत्रों में रजोनिवृत्त महिलाओं के बीच जीवन की गुणवत्ता पर संरचित व्यायाम कार्यक्रम का प्रभाव: एक यादृच्छिक नियंत्रित परीक्षण।

2. **अध्ययन जांचकर्ता:**

- **छात्र:** (नाम, विभाग): प्रिया, M.Sc. नर्सिंग (प्रसूति एवं स्त्री रोग), नर्सिंग कॉलेज
- **गाइड** (नाम, विभाग): डॉ. नसीमा शफकत, (प्रसूति एवं स्त्री रोग विशेषज्ञ), नर्सिंग कॉलेज
- **सह-गाइड (**नाम, विभाग): श्रीमती गीता भारद्वाज, प्रसूति एवं स्त्री रोग, नर्सिंग कॉलेज

3. **परिचय**:

हम एम्स भोपाल में रजोनिवृत्त महिलाओं के बीच जीवन की गुणवत्ता पर संरचित व्यायाम कार्यक्रम के प्रभाव का आकलन करने के लिए एक शोध अध्ययन कर रहे हैं। रजोनिवृत्ति एक महिला के जीवन में एक प्राकृतिक चरण है जो अक्सर शारीरिक और भावनात्मक दोनों तरह के विभिन्न परिवर्तनों के साथ आता है। हमारा मानना है कि नियमित व्यायाम में संलग्न होने से इस महत्वपूर्ण जीवन संक्रमण के दौरान समग्र कल्याण और जीवन की गुणवत्ता पर सकारात्मक प्रभाव पड़ सकता है। इस अध्ययन में, हम एक यादृच्छिक नियंत्रित परीक्षण करने की योजना बना रहे हैं, जिसका अर्थ है कि प्रतिभागियों को व्यायाम समूह या नियंत्रण समूह को यादृच्छिक रूप से सौंपा जाएगा। व्यायाम समूह एक सावधानीपूर्वक डिजाइन और पर्यवेक्षित व्यायाम कार्यक्रम का पालन करेगा, जबकि नियंत्रण समूह अपनी सामान्य गतिविधियों के साथ जारी रहेगा। इस शोध का लक्ष्य यह समझना है कि एक संरचित व्यायाम कार्यक्रम में भाग लेने से रजोनिवृत्त महिलाओं के लिए जीवन की बेहतर गुणवत्ता में कैसे योगदान हो सकता है। इस अध्ययन में आपकी भागीदारी महत्वपूर्ण है, क्योंकि यह हमें रजोनिवृत्ति के दौरान व्यायाम के संभावित लाभों में मूल्यवान अंतर्दृष्टि इकट्ठा करने में मदद करेगा।

4. **अध्ययन का उद्देश्य:**

इस अध्ययन का मुख्य उद्देश्य यह पता लगाना है कि क्या एक नियमित व्यायाम कार्यक्रम भोपाल के विशिष्ट क्षेत्रों में रजोनिवृत्ति से गुजर रही महिलाओं के लिए जीवन की गुणवत्ता में सकारात्मक बदलाव ला सकता है। सरल शब्दों में, हम यह पता लगाने की कोशिश कर रहे हैं कि क्या व्यायाम रजोनिवृत्ति से गुजरने वाली महिलाओं को कैसा महसूस होता है और अपने दैनिक जीवन जीने पर सकारात्मक प्रभाव डाल सकता है। इस अध्ययन में आपकी भागीदारी हमें इस महत्वपूर्ण जीवन परिवर्तनकाल के दौरान व्यायाम के संभावित लाभों के बारे में अधिक समझने में मदद करेगी।

5. **भाग लेना - इसमें क्या शामिल है:**

इस अध्ययन में भाग लेने में या तो व्यायाम समूह या नियंत्रण समूह में शामिल होने की प्रतिबद्धता शामिल है। यदि आपको व्यायाम समूह को सौंपा गया है, तो आप रजोनिवृत्त महिलाओं के अनुरूप डिज़ाइन किए गए सावधानीपूर्वक संरचित व्यायाम कार्यक्रम में संलग्न होंगे। इसमें आपकी व्यक्तिगत प्राथमिकताओं और शारीरिक स्थिति के आधार पर एरोबिक व्यायाम, शक्ति प्रशिक्षण या लचीलापन अभ्यास जैसी गतिविधियां शामिल हो सकती हैं। यदि आपको नियंत्रण समूह को सौंपा गया है, आप किसी भी निर्धारित व्यायाम आहार के बिना अपनी

सामान्य दैनिक गतिविधियों को जारी रखेंगे। अध्ययन के दौरान, हम आपकी प्रगति की बारीकी से निगरानी करेंगे, और हमारी टीम एक सहज और आरामदायक अनुभव सुनिश्चित करने के लिए मार्गदर्शन, सहायता और नियमित मार्गदर्शन प्रदान करेगी।

a. **क्या मुझे भाग लेना चाहिए?**हम आपको आश्वस्त करना चाहते हैं कि आपकी भागीदारी पूरी तरह से स्वैच्छिक है, और पूरे अध्ययन में आपकी गोपनीयता की रक्षा की जाएगी। हम आपको पूरे शोध के दौरान सभी आवश्यक जानकारी, समर्थन और मार्गदर्शन प्रदान करेंगे। भाग नहीं लेने का निर्णय, या किसी भी समय वापस लेने का निर्णय, किसी भी तरह से आपके अधिकारों या चिकित्सा देखभाल को प्रभावित नहीं करेगा।

b. अगर मैं भाग लेता हूं तो मुझसे क्या उम्मीद की जाती है?

यदि आप इस अध्ययन में भाग लेना चुनते हैं, तो आपकी भागीदारी में यादृच्छिक असाइनमेंट के आधार पर व्यायाम समूह या नियंत्रण समूह में शामिल होना शामिल होगा। यदि आप व्यायाम समूह में हैं, तो आपको रजोनिवृत्त महिलाओं के लिए डिज़ाइन किए गए एक संरचित व्यायाम कार्यक्रम में भाग लेना होगा। इसमें एरोबिक व्यायाम, शक्ति प्रशिक्षण, या लचीलापन अभ्यास जैसी गतिविधियों में संलग्न होना शामिल हो सकता है, जो आपकी प्राथमिकताओं और शारीरिक स्थिति के अनुरूप है।

आपके असाइन किए गए समूह के बावजूद, हमें अध्ययन दिशानिर्देशों का पालन करने और किसी भी निर्धारित चेक-इन या आकलन में भाग लेने के लिए आपकी प्रतिबद्धता की आवश्यकता होगी। इनमें आपकी प्रगति और कल्याण की निगरानी के लिए हमारी शोध टीम के साथ सामयिक बैठकें शामिल हो सकती हैं। आपकी सक्रिय भागीदारी और आपके अनुभवों के बारे में ईमानदार संचार अध्ययन की सफलता के लिए महत्वपूर्ण हैं।

i. हम आपके किसी भी प्रश्न या चिंताओं को संबोधित करने के लिए उपलब्ध हैं, और हम इस महत्वपूर्ण शोध प्रयास में शामिल होने के आपके विचार की सराहना करते हैं।

c. अध्ययन में मेरा हिस्सा कब तक चलेगा?

अध्ययन में आपकी भागीदारी की अवधि अनुसंधान के लिए उल्लिखित विशिष्ट समयरेखा पर निर्भर करेगी। आम तौर पर, आपकी भागीदारी 6-8 सप्ताह की हो सकती है, और यह अध्ययन की शुरुआत में आपको स्पष्ट रूप से सूचित किया जाएगा। अध्ययन की अवधि हमें व्यापक जानकारी इकट्ठा करने और समय के साथ किसी भी संभावित परिवर्तन का आकलन करने की अनुमति देने के लिए डिज़ाइन की गई है।

d. क्या मुझे अतिरिक्त यात्राओं के लिए आना होगा या अध्ययन के लिए अतिरिक्त जांच से गुजरना होगा?

अध्ययन में अध्ययन योजना में उल्लिखित निर्धारित बैठक और आकलन शामिल होंगे। ये बैठक आपकी प्रगति की निगरानी और मूल्यवान डेटा एकत्र करने के लिए आवश्यक हैं। भाग लेते समय, आपको नियमित चेक-इन या आकलन में भाग लेने की आवश्यकता हो सकती है, जो आपको पहले से सूचित किया जाएगा। प्रारंभ में जो बताया गया है, उससे परे किसी भी अतिरिक्त बैठक या जांच पर आपके साथ स्पष्ट रूप से चर्चा की जाएगी, और आगे बढ़ने से पहले आपकी सहमति प्राप्त की जाएगी। आपका आराम और सुविधा हमारे लिए महत्वपूर्ण विचार हैं, और हम आपके समय पर किसी भी अतिरिक्त बोझ को कम करने का प्रयास करते हैं।

e. **भाग लेने में संभावित लाभ क्या हैं?**

इस अध्ययन में भाग लेने से कई संभावित लाभ हो सकते हैं। व्यायाम समूह के लोगों के लिए, संरचित व्यायाम कार्यक्रम में संलग्नता से समग्र शारीरिक स्वास्थ्य, फिटनेस और कल्याण में सुधार हो सकता है। व्यायाम मूड, ऊर्जा के स्तर और नींद की गुणवत्ता पर सकारात्मक प्रभाव से जुड़ा हुआ है, जो रजोनिवृत्ति परिवर्तनकाल के दौरान आपके दैनिक जीवन को बढ़ा सकता है।

इसके अतिरिक्त, अध्ययन का हिस्सा होने से आपको रजोनिवृत्त महिलाओं के लिए व्यायाम के संभावित लाभों के बारे में वैज्ञानिक ज्ञान में योगदान करने की अनुमति मिलती है। आपकी भागीदारी महिलाओं के स्वास्थ्य अनुसंधान में प्रगति में योगदान कर सकती है, संभावित रूप से दूसरों को लाभान्वित कर सकती है जो भविष्य में इसी तरह के अनुभवों का सामना कर सकते हैं।

यह ध्यान रखना महत्वपूर्ण है कि जबकि संभावित लाभ का अनुमान है, व्यक्तिगत प्रतिक्रियाएं भिन्न हो सकती हैं। शोध टीम पूरे अध्ययन में आपकी सुरक्षा और कल्याण सुनिश्चित करने के लिए प्रतिबद्ध है, और हम आपके और अध्ययन में शामिल अन्य लोगों के लिए संभावित लाभों को अनुकूलित करने के लिए आपके अनुभवों के बारे में खुले संचार को प्रोत्साहित करते हैं।

f. **भाग लेने के संभावित नुकसान और जोखिम क्या हैं?**

अध्ययन के कारण कोई बड़ा नुकसान या जोखिम नहीं है। हालांकि भाग लेने का निर्णय लेने से पहले इन कारकों से अवगत होना महत्वपूर्ण है।

g. **समय प्रतिबद्धता:**

   i. अध्ययन में व्यायाम सत्र, आकलन और अनुवर्ती नियुक्तियों में भाग लेने के लिए एक महत्वपूर्ण समय प्रतिबद्धता की आवश्यकता हो सकती है। यह व्यस्त कार्यक्रम वाले व्यक्तियों के लिए एक चुनौती हो सकता है।

ii. असुविधा या थकान: एक नए व्यायाम कार्यक्रम में संलग्न होने से अस्थायी असुविधा, मांसपेशियों में दर्द या थकान हो सकती है। जबकि ये शारीरिक गतिविधि के शुरुआती चरणों के दौरान आम हैं, किसी भी लगातार या गंभीर असुविधा के बारे में जागरूक होना और रिपोर्ट करना आवश्यक है।

iii. कोई गारंटीकृत लाभ नहीं: जबकि अध्ययन का उद्देश्य व्यायाम कार्यक्रम के संभावित लाभों का पता लगाना है, इस बात की कोई गारंटी नहीं है कि प्रतिभागियों को सकारात्मक परिणामों का अनुभव होगा। व्यायाम के लिए व्यक्तिगत प्रतिक्रियाएं भिन्न हो सकती हैं, और कुछ प्रतिभागियों को जीवन की गुणवत्ता में महत्वपूर्ण सुधार नहीं दिख सकता है।

शोध टीम इन जोखिमों को कम करने और पूरे अध्ययन में आपकी सुरक्षा सुनिश्चित करने के लिए प्रतिबद्ध है। भाग लेने का निर्णय लेने से पहले, आपके पास अपनी भागीदारी के बारे में सूचित निर्णय लेने के लिए अनुसंधान टीम के साथ किसी भी चिंता या प्रश्न पर चर्चा करने का अवसर होगा। इसके अतिरिक्त, अध्ययन के दौरान चल रहे संचार किसी भी उभरते मुद्दों को समय पर संबोधित करने की अनुमति देगा।

h. **मुझसे एकत्र की गई जानकारी का क्या होता है?**

एकत्र की गई सभी जानकारी को सख्ती से गोपनीय रखा जाएगा और अनुसंधान टीम को छोड़कर किसी के साथ साझा नहीं किया जाएगा। अध्ययन के परिणाम समूह डेटा के रूप में रिपोर्ट किए जाएंगे और किसी भी तरह से आपकी पहचान नहीं उजागर करेंगे।

i. **क्या होगा अगर मैं अध्ययन में भाग लेने के बारे में अपना मन बदलता हूं?**

आप बिना किसी नुकसान या दंड के अध्ययन के दौरान किसी भी समय अपना मन बदलने और वापस लेने के हकदार हैं।

j. **अधिक जानकारी के लिए मैं किससे संपर्क करूं या यदि मेरे पास और प्रश्न या चिंताएं हैं?**

यदि आप कोई जानकारी चाहते हैं या आपके कोई प्रश्न या चिंताएं हैं, तो आप संपर्क कर सकते हैं:

सुश्री प्रिया
स्नातकोत्तर छात्र,
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डॉ. अंकुर जोशी
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इंस्टीट्यूट एथिक्स कमेटी – छात्र अनुसंधान
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ANNEXURE 12

प्रतिभागी सूचना सहमति प्रपत्र

[PARTICIPANT INFORMED CONSENT FORM (PICF)]

इस अध्ययन के लिए प्रतिभागी का पहचान नंबरः …….....

Participant Identification Number for this Study: ……...

अनुसंधान का शीर्षकः .....

Title of Project : Effect of structured exercise program on quality of life among postmenopausal women in selected areas of Bhopal: A randomised controlled trial.

शोधकर्ता छात्र का नाम .....फोन नं:.....

Name of Student Investigator : Priya Tel No.(s) : 9416131459

शोध मार्गदर्शक का नाम : ……..…….....

Name of Thesis Guide : Dr. Naseema Shafqat

मैंने दिनांक 20.08.2022 के सूचना पत्रक संस्करण II में दिए गए सभी तथ्यों को सावधानीपूर्वक पढ़ लिया है/ मुझे अपनी भाषा में स्पष्ट रूप से विस्तारपूर्वक समझा दिया गया है, और मैंने तथ्यों को पूर्णतः समझ लिया है। मैं पुष्टि करता/ करती हूँ, कि मुझे सवाल पूछने के अवसर प्रदान किए गए। The contents of the information sheet version II dated 20 August 2022 that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

मुझे इस अध्ययन की प्रकृति एवं उद्देश्य और इसके संभावित जोखिमों / लाभों तथा अध्ययन की अनुमानित अवधि एवं अन्य प्रासंगिक जानकारी के बारे में विस्तारपूर्वक समझा दिया गया है। मुझे पता है कि इस अध्ययन में मेरी भागीदारी स्वैच्छिक है तथा मैं इस अध्ययन से किसी भी समय बिना कोई कारण बताए, अपना नाम वापस लेने के लिए स्वतंत्र हूं और नाम वापस लेने पर मेरी चिकित्सा देखभाल या कानूनी अधिकारों पर कोई प्रभाव नहीं पड़ेगा। The nature and purpose of the study and its potential risks/benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.

मैं समझता/समझती हूं कि इस अनुसंधान में मेरी भागीदारी से मेरे बारे में एकत्र की गई जानकारी और मेरे चिकित्सीय दस्तावेजों के किसी भी भाग को एम्स के जिम्मेदार व्यक्तियों द्वारा ही देखा जाएगा। मैं इन व्यक्तियों को मेरे रिकॉर्ड प्राप्त करने की अनुमति प्रदान करता/ करती हूँ। I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from AIIMS. I give permission for this individuals to have access to my records.

मैं उक्त अध्ययन में भाग लेने के लिए सहमत हूं/I agree to take part in the above study.

_____

(प्रतिभागी के हस्ताक्षर / बांए अंगूठे का निशान) (Signature/Left Thumb Impression)

दिनांक/Date……स्थान/Place …….....……

प्रतिभागी का नाम/Name of the participant…….....

पिता/पति/पत्नी का नाम /Son/Daughter/Spouse of…….

डाक का पूरा पता /Complete Postal Address ……....

अगर अशिक्षित हों / If illiterate.

सूचना पत्र को प्रतिभागी को पढ़ा और समझाया गया है और प्रश्न पूछने का अवसर दिया गया है। मैं पुष्टि करता हूं कि व्यक्ति ने स्वतंत्र रूप से अपनी सहमति दी है ।

The information sheet has been read and explained to the participant and given the opportunity to ask questions. I confirm that the individual has given consent freely.

कानूनी रूप से स्वीकार्य प्रतिनिधि या निष्पक्ष गवाह के हस्ताक्षर

Signature of Legally acceptable representative or impartial witness.

दिनांक/Date

एलएआर या निष्पक्ष गवाह का नाम / Name of LAR or impartial witness.

पता / Address :-

प्रमाणित किया जाता है कि उक्त सहमति मेरी उपस्थिति में प्राप्त की गई ।

This is to certify that the above consent has been obtained in my presence._____

छात्र शोधकर्ता के हस्ताक्षर	दिनांक…….	स्थान…….
Signature of the student Investigator	Date ……	Place ……

ANNEXURE 13

Sociodemographic Profile and Homogeneity of Characteristics Between Groups (N=90)

S.No.	Variables	**Interventional group (n=45)**		**Control group (n = 45)**		Fisher exact/ Chi-square test
		Frequency	Percentage (%)	Frequency	Percentage (%)	
1.	**Age (in years)**					0.56
	45-50	11	24.4	7	15.6	
	50-55	24	53.3	27	60.4	
	55-60	10	22.2	11	24.4	
2.	**Religion**					1.00
	Hindu	43	95.6	43	95.6	
	Muslim	2	4.4	2	4.4	
3.	**Socio economic class**					0.84
	Upper middle	8	17.8	6	13.3	
	Lower middle	34	75.6	36	80	
	Upper lower	3	6.7	3	6.7	
4.	**Marital status**					0.59
	Married	37	82.2	35	77.8	

	Widow	8	17.8	10	22.2	
5.	**Type of family**					0.83
	Joint	22	48.9	21	46.7	
	Nuclear	23	51.1	24	53.3	
6.	**Availability of support system**					0.74
	Self help	31	68.9	31	68.9	
	Friends	5	11.1	7	15.6	
	Relatives	9	20.0	7	15.6	
7.	**Age of menarche**					0.51
	10-15 yrs	15	33.3	27	60	
	> 15 yrs	30	66.7	18	40	
8.	**No. of children**					0.21
	1-3	32	71.1	37	82.2	
	>3	13	28.9	8	17.8	
9.	**Age of menopause**					0.69
	<45 yrs	4	8.9	3	6.7	
	45-50 yrs	41	91.1	42	93.3	
10.	**Type of menopause**					

	Natural	43	95.6	45	100	0.15
	Surgical	2	4.4	0	0	
11.	**Duration of attainment of menopause, in years**					
	<5	25	55.6	23	51.1	0.47
	5-10	17	37.8	21	46.7	
	>10	3	6.7	1	2.2	
12.	**Do you smoke?**					
	No	44	97.8	45	100	0.31
	Yes	1	2.2	0	0	
13.	**Do you consume alcohol?**					
	No	45	100	45	100	
14.	**BMI**					
	Normal	26	57.8	22	48.9	0.64
	Overweight	13	28.9	17	37.8	
	Obese	6	13.3	6	13.3	
15.	**Physical activity**					
	Sedentary	10	22.2	8	17.8	0.784
	Light	18	40.0	21	46.7	

	Moderate	17	37.8	16	35.6	

ANNEXURE 14

Master Sheet

	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	S12	S13	S14	S15
w1	1	1	3	1	2	2	2	1	2	1	1	1	1	2	2
w2	2	1	2	3	2	1	2	1	2	1	1	1	1	2	2
w3	2	1	3	3	2	1	2	1	2	1	1	1	1	1	3
w4	2	1	2	1	2	1	2	1	2	1	2	1	1	2	2
w5	3	1	3	1	1	1	2	1	2	1	2	1	1	2	2
w6	2	1	3	3	1	3	3	1	2	1	1	1	1	1	2
w7	1	1	3	1	2	2	2	1	1	1	1	1	1	1	3
w8	3	1	2	1	2	1	2	2	2	1	2	1	1	3	1
w9	2	1	3	1	1	3	2	2	2	1	1	1	1	2	1
w10	2	1	3	1	1	2	2	1	2	1	2	1	1	3	1
w11	3	1	4	1	2	1	2	2	1	2	3	1	1	1	3
w12	3	1	3	1	2	1	3	2	1	2	3	1	1	1	2
w13	2	1	3	1	2	2	3	2	2	1	1	1	1	1	2
w14	2	1	4	1	2	1	3	2	2	1	2	1	1	1	2
w15	1	1	3	1	2	1	2	1	2	1	1	1	1	1	3
w16	1	1	2	1	1	1	3	1	2	1	1	1	1	1	3
w17	2	1	3	1	1	1	3	2	2	1	1	1	1	1	2
w18	2	1	3	3	1	1	2	2	2	1	2	1	1	2	1
w19	2	1	3	1	2	3	2	1	2	1	2	1	1	1	3
w20	2	1	3	1	2	1	2	1	2	1	1	1	1	1	3
w21	3	1	2	3	1	3	3	1	2	1	3	2	1	3	1
w22	1	1	3	1	1	1	2	1	2	1	1	1	1	1	3
w23	1	1	3	1	2	1	2	1	2	1	1	1	1	1	2
w24	2	1	3	1	1	3	3	1	2	1	1	1	1	1	3
w25	1	1	3	1	2	1	2	1	2	1	1	1	1	1	3
w26	1	1	3	1	1	1	2	1	2	1	1	1	1	1	2
w27	3	1	2	1	1	3	2	1	2	1	2	1	1	3	1
w28	2	1	3	3	2	1	3	1	2	1	1	1	1	1	2
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